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Braido

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(54) **COLLAPSIBLE-EXPANDABLE PROSTHETIC HEART VALVES WITH STRUCTURES FOR CLAMPING NATIVE TISSUE**

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This patent is subject to a terminal disclaimer.

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A61F 2/24 (2006.01)

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(58) **Field of Classification Search**
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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,409,013 A 11/1968 Berry
3,467,102 A 9/1969 Fogarty
(Continued)

FOREIGN PATENT DOCUMENTS

DE 2246526 3/1973
DE 19532846 A1 3/1997
(Continued)

OTHER PUBLICATIONS

"Transluminal Implantation of Artificial Heart Valves", Andersen, H. R., et al., European Heart Journal, vol. 13, No. 5, May 1992, pp. 704-708.
(Continued)

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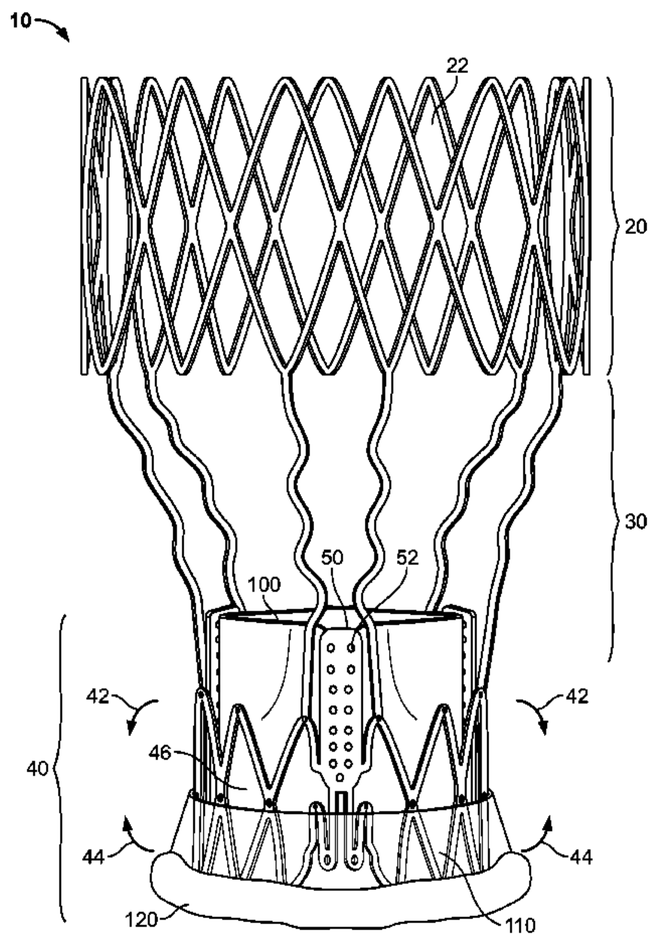
(57) **ABSTRACT**

A prosthetic heart valve is designed to be circumferentially collapsible for less invasive delivery into the patient. At the implant site the valve re-expands to a larger circumferential size, i.e., the size that it has for operation as a replacement for one of the patient's native heart valves. The valve includes structures that, at the implant site, extend radially outwardly to engage tissue structures above and below the native heart valve annulus. These radially outwardly extending structures clamp the native tissue between them and thereby help to anchor the prosthetic valve at the desired location in the patient.

22 Claims, 18 Drawing Sheets



Related U.S. Application Data

continuation of application No. 14/688,357, filed on Apr. 16, 2015, now Pat. No. 10,426,604, which is a continuation of application No. 11/906,133, filed on Sep. 28, 2007, now Pat. No. 9,532,868.

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,548,417	A	12/1970	Kischer	
3,587,115	A	6/1971	Shiley	
3,657,744	A	4/1972	Ersek	
3,671,979	A	6/1972	Moulopoulos	
3,714,671	A	2/1973	Goodenough	
3,755,823	A	9/1973	Hancock	
3,983,581	A	10/1976	Angell	
4,035,849	A	7/1977	Angell	
4,056,854	A	11/1977	Boretos	
4,106,129	A	8/1978	Carpentier	
4,222,126	A	9/1980	Boretos	
4,265,694	A	5/1981	Boretos	
4,275,469	A	6/1981	Gabbay	
4,297,749	A	11/1981	Davis	
RE30,912	E	4/1982	Hancock	
4,339,831	A	7/1982	Johnson	
4,343,048	A	8/1982	Ross	
4,345,340	A	8/1982	Rosen	
4,373,216	A	2/1983	Klawitter	
4,406,022	A	9/1983	Roy	
4,470,157	A	9/1984	Love	
4,491,986	A	1/1985	Gabbay	
4,535,483	A	8/1985	Klawitter	
4,574,803	A	3/1986	Storz	
4,592,340	A	6/1986	Boyles	
4,605,407	A	8/1986	Black	
4,612,011	A	9/1986	Kautzky	
4,643,732	A	2/1987	Pietsch	
4,655,771	A	4/1987	Wallsten	
4,692,164	A	9/1987	Dzemeshkevich	
4,733,665	A	3/1988	Palmaz	
4,759,758	A	7/1988	Gabbay	
4,762,128	A	8/1988	Rosenbluth	
4,777,951	A	10/1988	Cribier	
4,787,899	A	11/1988	Lazarus	
4,796,629	A	1/1989	Grayzel	
4,797,901	A	1/1989	Goerne	
4,829,990	A	5/1989	Joachim	
4,851,001	A	7/1989	Taheri	
4,856,516	A	8/1989	Hillstead	
4,878,495	A	11/1989	Grayzel	
4,878,906	A	11/1989	Lindemann	
4,883,458	A	11/1989	Shiber	
4,922,905	A	5/1990	Strecker	
4,966,604	A	10/1990	Reiss	
4,979,939	A	12/1990	Shiber	
4,986,830	A	1/1991	Owens	
4,994,077	A	2/1991	Dobben	
5,007,896	A	4/1991	Shiber	
5,026,366	A	6/1991	Leckrone	
5,032,128	A	7/1991	Alonso	
5,037,434	A	8/1991	Lane	
5,047,041	A	9/1991	Samuels	
5,059,177	A	10/1991	Towne	
5,080,668	A	1/1992	Bolz	
5,085,635	A	2/1992	Cragg	
5,089,015	A	2/1992	Ross	
5,152,771	A	10/1992	Sabbaghian	
5,163,953	A	11/1992	Vince	
5,167,628	A	12/1992	Boyles	
5,192,297	A	3/1993	Hull	
5,258,023	A	11/1993	Reger	
5,266,073	A	11/1993	Wall	
5,282,847	A	2/1994	Trescony	
5,295,958	A	3/1994	Shturman	
5,332,402	A	7/1994	Teitelbaum	
5,360,444	A	11/1994	Kusuhara	
5,370,685	A	12/1994	Stevens	
5,397,351	A	3/1995	Pavcnik	
5,411,055	A	5/1995	Kane	
5,411,552	A	5/1995	Andersen	
5,415,664	A	5/1995	Pinchuk	
5,415,667	A	5/1995	Frater	
5,443,446	A	8/1995	Shturman	
5,480,423	A	1/1996	Ravenscroft	
5,480,424	A	1/1996	Cox	
5,500,014	A	3/1996	Quijano	
5,545,209	A	8/1996	Roberts	
5,545,214	A	8/1996	Stevens	
5,549,665	A	8/1996	Vesely	
5,554,185	A	9/1996	Block	
5,571,175	A	11/1996	Vanney	
5,591,185	A	1/1997	Kilmer	
5,607,464	A	3/1997	Trescony	
5,609,626	A	3/1997	Quijano	
5,628,786	A	5/1997	Banas	
5,639,274	A	6/1997	Fischell	
5,665,115	A	9/1997	Cragg	
5,693,088	A	12/1997	Lazarus	
5,716,417	A	2/1998	Girard	
5,728,068	A	3/1998	Leone	
5,741,324	A *	4/1998	Glastra	A61F 2/07 128/897
5,749,890	A	5/1998	Shaknovich	
5,756,476	A	5/1998	Epstein	
5,769,812	A	6/1998	Stevens	
5,769,882	A	6/1998	Fogarty	
5,776,188	A	7/1998	Shepherd	
5,800,508	A	9/1998	Goicoechea	
5,840,081	A	11/1998	Andersen	
5,843,161	A	12/1998	Solovay	
5,843,167	A	12/1998	Dwyer	
5,855,597	A	1/1999	Jayaraman	
5,855,601	A	1/1999	Bessler	
5,855,602	A	1/1999	Angell	
5,925,063	A	7/1999	Khosravi	
5,928,281	A	7/1999	Huynh	
5,935,163	A	8/1999	Gabbay	
5,957,949	A	9/1999	Leonhardt	
5,961,549	A	10/1999	Nguyen	
6,015,431	A	1/2000	Thornton	
6,027,525	A	2/2000	Suh	
6,045,576	A	4/2000	Starr	
6,077,297	A	6/2000	Robinson	
6,083,257	A	7/2000	Taylor	
6,090,140	A	7/2000	Gabbay	
6,110,198	A	8/2000	Fogarty	
6,132,473	A	10/2000	Williams	
6,168,614	B1	1/2001	Andersen	
6,171,335	B1	1/2001	Wheatley	
6,174,327	B1	1/2001	Mertens	
6,210,408	B1	4/2001	Chandrasekaran	
6,214,036	B1	4/2001	Letendre	
6,217,585	B1	4/2001	Houser	
6,221,091	B1	4/2001	Khosravi	
6,231,602	B1	5/2001	Carpentier	
6,245,102	B1	6/2001	Jayaraman	
6,264,691	B1	7/2001	Gabbay	
6,267,783	B1	7/2001	Letendre	
6,299,637	B1	10/2001	Shaolian	
6,302,906	B1	10/2001	Goicoechea	
6,306,164	B1	10/2001	Kujawski	
6,312,465	B1	11/2001	Griffin	

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,350,277	B1	2/2002	Kocur	
6,352,554	B2	3/2002	De Paulis	
6,368,348	B1	4/2002	Gabbay	
6,419,695	B1	7/2002	Gabbay	
6,425,916	B1	7/2002	Garrison	
6,440,164	B1	8/2002	DiMatteo	
6,454,799	B1	9/2002	Schreck	
6,458,153	B1	10/2002	Bailey	
6,461,382	B1	10/2002	Cao	
6,468,660	B2	10/2002	Ogle	
6,482,228	B1	11/2002	Norred	
6,488,702	B1	12/2002	Besselink	
6,488,704	B1	12/2002	Connelly	
6,517,576	B2	2/2003	Gabbay	
6,533,810	B2	3/2003	Hankh	
6,569,196	B1	5/2003	Vesely	
6,582,462	B1	6/2003	Andersen	
6,582,464	B2	6/2003	Gabbay	
6,605,112	B1	8/2003	Moll	
6,610,088	B1	8/2003	Gabbay	
6,623,518	B2	9/2003	Thompson	
6,652,578	B2	11/2003	Bailey	
6,685,625	B2	2/2004	Gabbay	
6,712,836	B1	3/2004	Berg	
6,716,244	B2	4/2004	Klaco	
6,719,789	B2	4/2004	Cox	
6,726,715	B2	4/2004	Sutherland	
6,729,356	B1	5/2004	Baker	
6,730,118	B2	5/2004	Spenser	
6,733,525	B2	5/2004	Yang	
6,767,362	B2	7/2004	Schreck	
6,780,510	B2	8/2004	Ogle	
6,783,556	B1	8/2004	Gabbay	
6,790,229	B1	9/2004	Berreklouw	
6,790,230	B2	9/2004	Beyersdorf	
6,814,746	B2	11/2004	Thompson	
6,814,754	B2	11/2004	Greenhalgh	
6,830,584	B1	12/2004	Seguin	
6,830,585	B1	12/2004	Artof	
6,837,902	B2	1/2005	Nguyen	
6,860,901	B1	3/2005	Baker	
6,869,444	B2	3/2005	Gabbay	
6,875,231	B2	4/2005	Anduiza	
6,893,460	B2	5/2005	Spenser	
6,908,481	B2	6/2005	Cribier	
6,911,040	B2	6/2005	Johnson	
6,951,573	B1	10/2005	Dilling	
7,018,406	B2	3/2006	Seguin	
7,018,408	B2	3/2006	Bailey	
7,025,780	B2	4/2006	Gabbay	
7,041,132	B2	5/2006	Quijano	
7,044,966	B2	5/2006	Svanidze	
7,101,396	B2	9/2006	Artof	
7,137,184	B2	11/2006	Schreck	
7,147,663	B1	12/2006	Berg	
7,160,322	B2	1/2007	Gabbay	
7,195,641	B2	3/2007	Palmaz	
7,198,646	B2	4/2007	Figulla	
7,201,772	B2	4/2007	Schwammenthal	
7,247,167	B2	7/2007	Gabbay	
7,252,682	B2	8/2007	Seguin	
7,261,732	B2	8/2007	Justino	
7,264,632	B2	9/2007	Wright	
7,267,686	B2	9/2007	DiMatteo	
7,276,078	B2	10/2007	Spenser	
7,276,084	B2	10/2007	Yang	
7,311,730	B2	12/2007	Gabbay	
7,320,704	B2	1/2008	Lashinski	
7,329,278	B2	2/2008	Seguin	
7,331,991	B2	2/2008	Kheradvar	
7,338,520	B2	3/2008	Bailey	
7,374,571	B2	5/2008	Pease	
7,374,573	B2	5/2008	Gabbay	
7,381,218	B2	6/2008	Schreck	
7,381,219	B2	6/2008	Salahieh	
7,393,360	B2	7/2008	Spenser	
7,399,315	B2	7/2008	Iobbi	
7,452,371	B2	11/2008	Pavcnik	
7,462,191	B2	12/2008	Spenser	
7,481,838	B2	1/2009	Carpentier	
7,510,572	B2	3/2009	Gabbay	
7,510,575	B2	3/2009	Spenser	
7,524,331	B2	4/2009	Birdsall	
7,527,647	B2	5/2009	Spence	
7,530,995	B2	5/2009	Quijano	
7,534,261	B2	5/2009	Friedman	
RE40,816	E	6/2009	Taylor	
7,585,321	B2	9/2009	Cribier	
7,597,711	B2	10/2009	Drews	
7,628,805	B2	12/2009	Spenser	
7,682,390	B2	3/2010	Seguin	
7,708,775	B2	5/2010	Rowe	
7,717,955	B2	5/2010	Lane	
7,731,742	B2	6/2010	Schlick	
7,748,389	B2	7/2010	Salahieh	
7,780,725	B2	8/2010	Haug	
7,799,069	B2	9/2010	Bailey	
7,803,185	B2	9/2010	Gabbay	
7,824,442	B2	11/2010	Salahieh	
7,837,727	B2	11/2010	Goetz	
7,846,203	B2	12/2010	Cribier	
7,846,204	B2	12/2010	Letac	
7,857,845	B2	12/2010	Stacchino	
7,871,435	B2	1/2011	Carpentier	
7,892,281	B2	2/2011	Seguin	
7,914,569	B2	3/2011	Nguyen	
7,951,197	B2	5/2011	Lane	
7,955,377	B2 *	6/2011	Melsheimer	A61F 2/2475 623/2.18
7,959,666	B2	6/2011	Salahieh	
7,959,672	B2	6/2011	Salahieh	
7,959,674	B2	6/2011	Shu	
7,967,857	B2	6/2011	Lane	
7,972,378	B2	7/2011	Tabor	
7,988,724	B2	8/2011	Salahieh	
7,993,394	B2	8/2011	Hariton	
8,016,877	B2	9/2011	Seguin	
8,038,708	B2 *	10/2011	Case	A61F 2/2475 623/1.24
D648,854	S	11/2011	Braido	
8,048,153	B2	11/2011	Salahieh	
8,052,741	B2	11/2011	Bruszewski	
8,052,749	B2	11/2011	Salahieh	
8,052,750	B2	11/2011	Tuval	
8,062,355	B2	11/2011	Figulla	
8,075,611	B2	12/2011	Millwee	
8,083,793	B2	12/2011	Lane	
D652,926	S	1/2012	Braido	
D652,927	S	1/2012	Braido	
D653,341	S	1/2012	Braido	
D653,342	S	1/2012	Braido	
D653,343	S	1/2012	Ness	
D654,169	S	2/2012	Braido	
D654,170	S	2/2012	Braido	
8,137,398	B2	3/2012	Tuval	
8,142,497	B2	3/2012	Friedman	
D660,432	S	5/2012	Braido	
D660,433	S	5/2012	Braido	
D660,967	S	5/2012	Braido	
8,182,528	B2	5/2012	Salahieh	
8,221,493	B2	7/2012	Boyle	
8,226,710	B2	7/2012	Nguyen	
8,230,717	B2	7/2012	Matonick	
8,231,670	B2	7/2012	Salahieh	
8,252,051	B2	8/2012	Chau	
8,308,798	B2	11/2012	Pintor	
8,313,525	B2	11/2012	Tuval	
8,313,526	B2 *	11/2012	Hoffman	A61F 2/2418 623/2.18
8,323,335	B2	12/2012	Rowe	
8,323,336	B2	12/2012	Hill	
8,343,213	B2	1/2013	Salahieh	
8,348,995	B2	1/2013	Tuval	
8,348,996	B2	1/2013	Tuval	

(56) **References Cited**

U.S. PATENT DOCUMENTS

8,348,998	B2	1/2013	Pintor	
8,349,000	B2	1/2013	Schreck	
8,366,769	B2	2/2013	Huynh	
8,403,983	B2	3/2013	Quadri	
8,408,214	B2	4/2013	Spenser	
8,414,643	B2	4/2013	Tuval	
8,425,593	B2	4/2013	Braido	
8,449,599	B2	5/2013	Chau	
8,449,604	B2	5/2013	Moaddeb	
8,454,685	B2	6/2013	Hariton	
8,454,686	B2	6/2013	Alkhatib	
8,465,540	B2	6/2013	Straubinger	
8,500,798	B2	8/2013	Rowe	
8,512,396	B2	8/2013	Styrc	
8,568,474	B2	10/2013	Yeung	
8,568,477	B2	10/2013	Lashinski	
8,579,962	B2	11/2013	Salahieh	
8,579,966	B2	11/2013	Seguin	
8,585,755	B2	11/2013	Chau	
8,591,575	B2	11/2013	Cribier	
8,597,349	B2	12/2013	Alkhatib	
8,603,159	B2	12/2013	Seguin	
8,603,160	B2	12/2013	Salahieh	
8,613,765	B2	12/2013	Bonhoeffer	
8,623,074	B2	1/2014	Ryan	
8,647,381	B2 *	2/2014	Essinger	A61F 2/2418 623/1.24
8,652,204	B2	2/2014	Quill	
8,663,322	B2	3/2014	Olli	
8,668,733	B2	3/2014	Haug	
8,673,000	B2	3/2014	Tabor	
8,685,080	B2	4/2014	White	
8,685,086	B2	4/2014	Navia	
8,728,154	B2 *	5/2014	Alkhatib	A61F 2/2418 623/1.26
8,747,459	B2	6/2014	Nguyen	
8,747,460	B2 *	6/2014	Tuval	A61F 2/2418 623/2.11
8,747,461	B2 *	6/2014	Centola	A61F 2/2418 623/1.26
8,764,820	B2	7/2014	Dehdashtian	
8,771,345	B2	7/2014	Tuval	
8,784,481	B2 *	7/2014	Alkhatib	A61F 2/2409 623/2.18
8,795,357	B2	8/2014	Yohanan	
8,801,776	B2	8/2014	House	
8,808,356	B2	8/2014	Braido	
8,828,078	B2	9/2014	Salahieh	
8,834,563	B2	9/2014	Righini	
8,840,661	B2	9/2014	Manasse	
8,840,663	B2	9/2014	Salahieh	
8,845,721	B2	9/2014	Braido	
8,876,894	B2	11/2014	Tuval	
8,876,895	B2	11/2014	Tuval	
8,920,492	B2	12/2014	Stacchino	
8,940,040	B2	1/2015	Shahriari	
8,945,209	B2	2/2015	Bonyuet	
8,961,595	B2	2/2015	Alkhatib	
8,974,523	B2	3/2015	Thill	
8,974,524	B2	3/2015	Yeung	
8,986,375	B2	3/2015	Garde	
8,992,608	B2	3/2015	Haug	
9,095,432	B2 *	8/2015	Cribier	A61F 2/2433
9,132,007	B2	9/2015	Menk	
9,168,129	B2	10/2015	Valdez	
9,186,249	B2	11/2015	Rolando	
9,308,087	B2	4/2016	Lane	
9,393,110	B2	7/2016	Levi	
9,398,951	B2 *	7/2016	Alkhatib	A61F 2/2418
9,414,910	B2	8/2016	Lim	
9,532,868	B2 *	1/2017	Braido	A61F 2/2409
9,572,660	B2 *	2/2017	Braido	A61L 27/3604
9,636,222	B2	5/2017	Oslund	
9,668,858	B2	6/2017	Morin	
9,675,451	B2	6/2017	Garde	
9,681,949	B2	6/2017	Braido	
9,713,529	B2	7/2017	Lane	
9,801,737	B2 *	10/2017	Hinchliffe	A61F 2/2475
9,820,851	B2 *	11/2017	Braido	A61F 2/2409
9,839,513	B2	12/2017	Essinger	
9,848,981	B2 *	12/2017	Suri	A61F 2/2418
9,889,004	B2	2/2018	Braido	
9,949,826	B2 *	4/2018	Alkhatib	A61F 2/2445
10,413,401	B2	9/2019	Eberhardt	
10,966,821	B2 *	4/2021	Delaloye	A61F 2/2409
11,090,153	B2 *	8/2021	Haarer	A61F 2/246
11,109,964	B2	9/2021	Hacohen	
11,337,800	B2	5/2022	Schreck	
11,337,812	B2 *	5/2022	Hill	A61B 90/39
11,382,740	B2 *	7/2022	Braido	A61F 2/2418
11,504,231	B2 *	11/2022	Carlino	A61F 2/2418
11,771,544	B2 *	10/2023	Essinger	A61F 2/2418 623/1.26
11,883,281	B2 *	1/2024	Hoang	A61F 2/2418
2001/0007956	A1	7/2001	Letac	
2001/0010017	A1	7/2001	Letac	
2001/0021872	A1	9/2001	Bailey	
2001/0027338	A1	10/2001	Greenberg	
2001/0041928	A1	11/2001	Pavcnik	
2002/0032481	A1	3/2002	Gabbay	
2002/0036220	A1	3/2002	Gabbay	
2002/0055774	A1	5/2002	Liddicoat	
2002/0138138	A1	9/2002	Yang	
2002/0173842	A1	11/2002	Buchanan	
2003/0023303	A1	1/2003	Palmaz	
2003/0027332	A1	2/2003	Lafrance	
2003/0036791	A1	2/2003	Philipp	
2003/0040792	A1	2/2003	Gabbay	
2003/0050694	A1	3/2003	Yang	
2003/0100939	A1	5/2003	Yodfat	
2003/0109924	A1	6/2003	Cribier	
2003/0114913	A1	6/2003	Spenser	
2003/0130726	A1	7/2003	Thorpe	
2003/0167089	A1	9/2003	Lane	
2003/0199963	A1	10/2003	Tower	
2003/0199971	A1	10/2003	Tower	
2003/0209835	A1 *	11/2003	Chun	A61F 2/2412 264/339
2003/0212454	A1	11/2003	Scott	
2003/0236567	A1	12/2003	Elliot	
2003/0236568	A1 *	12/2003	Hojeibane	A61F 2/2415 623/2.18
2004/0019374	A1 *	1/2004	Hojeibane	A61F 2/2415 623/2.38
2004/0033364	A1	2/2004	Spiridigliozzi	
2004/0039436	A1	2/2004	Spenser	
2004/0049262	A1	3/2004	Obermiller	
2004/0082989	A1	4/2004	Cook	
2004/0093060	A1	5/2004	Seguin	
2004/0093075	A1	5/2004	Kuehne	
2004/0111111	A1	6/2004	Lin	
2004/0186565	A1	9/2004	Schreck	
2004/0193261	A1	9/2004	Berreklouw	
2004/0210304	A1	10/2004	Seguin	
2004/0260389	A1 *	12/2004	Case	A61F 2/2475 623/2.38
2005/0033398	A1	2/2005	Seguin	
2005/0043790	A1	2/2005	Seguin	
2005/0075718	A1	4/2005	Nguyen	
2005/0075725	A1	4/2005	Rowe	
2005/0096726	A1	5/2005	Sequin	
2005/0113910	A1	5/2005	Paniagua	
2005/0137682	A1 *	6/2005	Justino	A61F 2/2418 623/2.14
2005/0137686	A1	6/2005	Salahieh	
2005/0137688	A1	6/2005	Salahieh	
2005/0137689	A1	6/2005	Salahieh	
2005/0137690	A1	6/2005	Salahieh	
2005/0137691	A1	6/2005	Salahieh	
2005/0137695	A1	6/2005	Salahieh	
2005/0137696	A1	6/2005	Salahieh	
2005/0137697	A1	6/2005	Salahieh	
2005/0137698	A1	6/2005	Salahieh	

(56) **References Cited**

U.S. PATENT DOCUMENTS

2005/0137699	A1	6/2005	Salahieh	
2005/0137701	A1	6/2005	Salahieh	
2005/0143809	A1	6/2005	Salahieh	
2005/0165477	A1	7/2005	Anduiza	
2005/0177228	A1	8/2005	Solem	
2005/0192665	A1	9/2005	Spenser	
2005/0197695	A1	9/2005	Stacchino	
2005/0203605	A1	9/2005	Dolan	
2005/0203616	A1	9/2005	Cribier	
2005/0234546	A1	10/2005	Nugent	
2005/0240200	A1	10/2005	Bergheim	
2005/0251251	A1	11/2005	Cribier	
2005/0256566	A1	11/2005	Gabbay	
2005/0283231	A1	12/2005	Haug	
2006/0004439	A1	1/2006	Spenser	
2006/0004442	A1	1/2006	Spenser	
2006/0008497	A1	1/2006	Gabbay	
2006/0025855	A1	2/2006	Lashinski	
2006/0025857	A1	2/2006	Bergheim	
2006/0052867	A1	3/2006	Revuelta	
2006/0058872	A1	3/2006	Salahieh	
2006/0074484	A1*	4/2006	Huber	A61F 2/2412 623/2.14
2006/0122692	A1	6/2006	Gilad	
2006/0129235	A1	6/2006	Seguin	
2006/0149350	A1	7/2006	Patel	
2006/0149360	A1	7/2006	Schwammenthal	
2006/0161249	A1	7/2006	Realyvasquez	
2006/0173532	A1	8/2006	Flagle	
2006/0178731	A1	8/2006	Tower	
2006/0178740	A1	8/2006	Stacchino	
2006/0195180	A1	8/2006	Kheradvar	
2006/0195183	A1	8/2006	Navia	
2006/0195186	A1	8/2006	Drews	
2006/0206202	A1	9/2006	Bonhoeffer	
2006/0229719	A1	10/2006	Marquez	
2006/0241744	A1	10/2006	Beith	
2006/0241745	A1	10/2006	Solem	
2006/0253191	A1	11/2006	Salahieh	
2006/0259120	A1	11/2006	Vongphakdy	
2006/0259134	A1	11/2006	Schwammenthal	
2006/0259135	A1	11/2006	Navia	
2006/0259136	A1	11/2006	Nguyen	
2006/0259137	A1*	11/2006	Artof	A61F 2/243 623/2.11
2006/0265056	A1	11/2006	Nguyen	
2006/0276813	A1	12/2006	Greenberg	
2006/0276874	A1	12/2006	Wilson	
2006/0287719	A1	12/2006	Rowe	
2007/0010876	A1	1/2007	Salahieh	
2007/0027534	A1	2/2007	Bergheim	
2007/0043435	A1	2/2007	Seguin	
2007/0050021	A1	3/2007	Johnson	
2007/0055358	A1	3/2007	Krolik	
2007/0067029	A1	3/2007	Gabbay	
2007/0073387	A1	3/2007	Forster	
2007/0093890	A1	4/2007	Eliasen	
2007/0100435	A1*	5/2007	Case	A61F 2/2418 623/901
2007/0112355	A1	5/2007	Salahieh	
2007/0112422	A1	5/2007	Dehdashtian	
2007/0118210	A1	5/2007	Pinchuk	
2007/0118214	A1	5/2007	Salahieh	
2007/0142907	A1	6/2007	Moaddeb	
2007/0162100	A1	7/2007	Gabbay	
2007/0162107	A1	7/2007	Haug	
2007/0168022	A1	7/2007	Eldridge	
2007/0198097	A1	8/2007	Zegdi	
2007/0203503	A1	8/2007	Salahieh	
2007/0208550	A1	9/2007	Cao	
2007/0213813	A1	9/2007	Von Segesser	
2007/0233228	A1	10/2007	Eberhardt	
2007/0239265	A1	10/2007	Birdsall	
2007/0239271	A1	10/2007	Nguyen	
2007/0244545	A1	10/2007	Birdsall	
2007/0244552	A1	10/2007	Salahieh	
2007/0255398	A1	11/2007	Yang	
2007/0270944	A1	11/2007	Bergheim	
2007/0282436	A1	12/2007	Pinchuk	
2007/0288087	A1	12/2007	Fearnot	
2008/0021546	A1	1/2008	Patz	
2008/0021552	A1	1/2008	Gabbay	
2008/0039934	A1	2/2008	Styrc	
2008/0071361	A1	3/2008	Tuval	
2008/0071363	A1	3/2008	Tuval	
2008/0071369	A1	3/2008	Tuval	
2008/0077236	A1	3/2008	Brice	
2008/0082164	A1	4/2008	Friedman	
2008/0097595	A1	4/2008	Gabbay	
2008/0114452	A1	5/2008	Gabbay	
2008/0125853	A1	5/2008	Bailey	
2008/0140189	A1	6/2008	Nguyen	
2008/0147179	A1	6/2008	Cai	
2008/0147183	A1	6/2008	Styrc	
2008/0154355	A1	6/2008	Benichou	
2008/0154356	A1	6/2008	Obermiller	
2008/0208327	A1	8/2008	Rowe	
2008/0208329	A1	8/2008	Bishop	
2008/0243245	A1	10/2008	Thambar	
2008/0243246	A1	10/2008	Ryan	
2008/0255662	A1	10/2008	Stacchino	
2008/0262602	A1	10/2008	Wilk	
2008/0269879	A1	10/2008	Sathe	
2009/0099653	A1	4/2009	Suri	
2009/0112309	A1	4/2009	Jaramillo	
2009/0138079	A1	5/2009	Tuval	
2009/0157175	A1*	6/2009	Benichou	A61F 2/2415 623/2.18
2009/0171447	A1	7/2009	Von Segesser	
2009/0192599	A1	7/2009	Ernest	
2009/0234443	A1	9/2009	Ottma	
2009/0248149	A1	10/2009	Gabbay	
2009/0264997	A1	10/2009	Salahieh	
2009/0276027	A1	11/2009	Glynn	
2009/0287296	A1	11/2009	Manasse	
2009/0287299	A1	11/2009	Tabor	
2010/0004740	A1	1/2010	Seguin	
2010/0036484	A1*	2/2010	Hariton	A61F 2/2433 623/2.18
2010/0049306	A1	2/2010	House	
2010/0082094	A1	4/2010	Quadri	
2010/0087907	A1	4/2010	Lattouf	
2010/0100176	A1	4/2010	Elizondo	
2010/0114305	A1	5/2010	Kang	
2010/0131055	A1	5/2010	Case	
2010/0168778	A1	7/2010	Braido	
2010/0168839	A1	7/2010	Braido	
2010/0168844	A1	7/2010	Toomes	
2010/0185277	A1*	7/2010	Braido	A61F 2/2409 623/2.37
2010/0191326	A1	7/2010	Alkhatib	
2010/0204781	A1*	8/2010	Alkhatib	A61F 2/2445 623/1.26
2010/0204785	A1*	8/2010	Alkhatib	A61F 2/2433 623/2.37
2010/0217382	A1	8/2010	Chau	
2010/0234940	A1	9/2010	Dolan	
2010/0249911	A1*	9/2010	Alkhatib	A61F 2/2418 623/1.26
2010/0249923	A1*	9/2010	Alkhatib	A61F 2/2409 623/2.18
2010/0262231	A1	10/2010	Tuval	
2010/0286768	A1	11/2010	Alkhatib	
2010/0298931	A1	11/2010	Quadri	
2011/0022157	A1*	1/2011	Essinger	A61F 2/2436 623/1.11
2011/0029066	A1*	2/2011	Gilad	A61F 2/2418 623/1.24
2011/0029072	A1	2/2011	Gabbay	
2011/0054466	A1	3/2011	Rothstein	
2011/0098800	A1*	4/2011	Braido	A61F 2/2418 623/1.26

(56) **References Cited**

U.S. PATENT DOCUMENTS

2011/0098802	A1*	4/2011	Braido	A61F 2/2412 623/2.11
2011/0137397	A1	6/2011	Chau	
2011/0166636	A1	7/2011	Rowe	
2011/0172765	A1	7/2011	Nguyen	
2011/0208283	A1	8/2011	Rust	
2011/0264206	A1	10/2011	Tabor	
2011/0282439	A1	11/2011	Thill	
2011/0301692	A1	12/2011	Seguin	
2011/0319988	A1	12/2011	Schankereli	
2012/0035719	A1	2/2012	Forster	
2012/0035722	A1	2/2012	Tuval	
2012/0046742	A1	2/2012	Tuval	
2012/0078347	A1	3/2012	Braido	
2012/0078353	A1	3/2012	Quadri	
2012/0078357	A1	3/2012	Conklin	
2012/0083878	A1	4/2012	Sequin	
2012/0083879	A1	4/2012	Eberhardt	
2012/0101572	A1	4/2012	Kovalsky	
2012/0123529	A1	5/2012	Levi	
2012/0179244	A1	7/2012	Schankereli	
2012/0215303	A1	8/2012	Quadri	
2012/0232646	A1	9/2012	Agathos	
2012/0271398	A1*	10/2012	Essinger	A61F 2/2412 623/1.11
2012/0277856	A1	11/2012	Spenser	
2012/0296418	A1	11/2012	Bonyuet	
2012/0303116	A1	11/2012	Gorman, III	
2012/0316642	A1	12/2012	Yu	
2013/0018458	A1	1/2013	Yohanan	
2013/0023984	A1	1/2013	Conklin	
2013/0144375	A1	6/2013	Giasolli	
2013/0150956	A1	6/2013	Yohanan	
2013/0197622	A1	8/2013	Mitra	
2013/0204359	A1	8/2013	Thubrikar	
2013/0211508	A1	8/2013	Lane	
2013/0218267	A1	8/2013	Braido	
2013/0261738	A1*	10/2013	Clague	A61F 2/2418 623/2.11
2013/0261739	A1*	10/2013	Kuehn	A61F 2/2412 623/2.11
2013/0274870	A1	10/2013	Lombardi	
2013/0274873	A1	10/2013	Delaloye	
2013/0331929	A1	12/2013	Mitra	
2013/0338765	A1	12/2013	Braido	
2013/0345786	A1	12/2013	Behan	
2014/0018915	A1*	1/2014	Biadillah	A61F 2/2418 623/2.17
2014/0121763	A1	5/2014	Duffy	
2014/0142694	A1	5/2014	Tabor	
2014/0155997	A1*	6/2014	Braido	A61F 2/2409 623/2.37
2014/0194981	A1	7/2014	Menk	
2014/0214157	A1	7/2014	Börtlein	
2014/0214159	A1	7/2014	Robert	
2014/0228946	A1	8/2014	Chau	
2014/0277388	A1*	9/2014	Skemp	A61F 2/2418 623/2.37
2014/0277428	A1	9/2014	Skemp	
2014/0303719	A1	10/2014	Cox	
2014/0324164	A1	10/2014	Gross	
2014/0343671	A1	11/2014	Yohanan	
2014/0350663	A1	11/2014	Braido	
2014/0350665	A1	11/2014	Braido	
2014/0350667	A1	11/2014	Braido	
2014/0350668	A1	11/2014	Delaloye	
2014/0350669	A1	11/2014	Gillespie	
2015/0025625	A1*	1/2015	Rylski	A61F 2/2412 623/2.14
2015/0216658	A1*	8/2015	Braido	A61F 2/2433 623/2.13
2015/0305860	A1	10/2015	Wang	
2015/0320556	A1	11/2015	Levi	
2016/0354201	A1	12/2016	Keogh	
2017/0049566	A1*	2/2017	Zeng	A61F 2/2418
2017/0325944	A1*	11/2017	Erzberger	A61F 2/2418
2019/0015191	A1*	1/2019	Berdajs	A61L 27/507
2022/0273437	A1*	9/2022	Kelley	A61F 2/2418
2024/0091006	A1*	3/2024	Anderson	A61F 2/2418
2024/0180694	A1*	6/2024	Loughnane	A61F 2/2418

FOREIGN PATENT DOCUMENTS

DE	19546692	A1	6/1997
DE	19907646	A1	8/2000
DE	10049812	A1	4/2002
DE	10049813	C1	4/2002
DE	10049814		4/2002
DE	10049815	A1	4/2002
DE	19857887	B4	5/2005
DE	10121210	B4	11/2005
DE	102005003632	A1	8/2006
DE	202008009610	U1	12/2008
EP	0103546	A1	3/1984
EP	0144167		6/1985
EP	0592410	A1	4/1994
EP	0850607	A1	7/1998
EP	0597967	B1	12/1999
EP	1000590	A1	5/2000
EP	1057460	A1	12/2000
EP	1088529	A2	4/2001
EP	1360942	A1	11/2003
EP	1570809	A1	9/2005
EP	1584306	A1	10/2005
EP	1598031	A2	11/2005
EP	1360942	B1	12/2005
EP	1926455	A2	6/2008
EP	2047824	A1	4/2009
EP	2254513	A1	12/2010
EP	2059192	B1	7/2011
EP	2537487	A1	12/2012
EP	2620125	A1	7/2013
EP	2749254	A1	7/2014
EP	2815725	A1	12/2014
FR	2788217	A1	7/2000
FR	2850008	A1	7/2004
FR	2847800	B1	10/2005
GB	2056023		3/1981
JP	2008541865	A	11/2008
JP	2011500241	A	1/2011
JP	2011522634	A	8/2011
JP	2011528256	A	11/2011
JP	2012504031	A	2/2012
SU	15898		6/1930
SU	1271508		11/1986
SU	1371700		2/1988
SU	1457921	A1	2/1989
WO	9117720	A1	11/1991
WO	9217118	A1	10/1992
WO	9301768	A1	2/1993
WO	9716133	A1	5/1997
WO	9724080	A1	7/1997
WO	9832412	A2	7/1998
WO	1998029057	A1	7/1998
WO	9913801	A1	3/1999
WO	9933414		7/1999
WO	9940964	A1	8/1999
WO	9947075	A1	9/1999
WO	2000018333	A1	4/2000
WO	2000041652	A1	7/2000
WO	200047139	A1	8/2000
WO	2001028459	A1	4/2001
WO	2001035878	A2	5/2001
WO	0149213	A2	7/2001
WO	0156500	A2	8/2001
WO	200162189	A1	8/2001
WO	2001054624	A1	8/2001
WO	2001054625	A1	8/2001
WO	0164137	A1	9/2001
WO	0166035	A2	9/2001
WO	0166037	A2	9/2001
WO	2001076510	A2	10/2001
WO	2002022054	A1	3/2002

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

WO	2002036048	A1	5/2002
WO	2002041789	A2	5/2002
WO	0247575	A2	6/2002
WO	2002049540	A2	6/2002
WO	02067782	A2	9/2002
WO	03037222	A2	5/2003
WO	2003047468	A1	6/2003
WO	2003075799	A1	9/2003
WO	2004016200	A1	2/2004
WO	2005062980	A2	7/2005
WO	2005070343	A1	8/2005
WO	2005087140	A1	9/2005
WO	2006014233	A2	2/2006
WO	2006034008	A2	3/2006
WO	2006041505	A1	4/2006
WO	2006073626	A2	7/2006
WO	2006124649	A2	11/2006
WO	2006127765	A1	11/2006
WO	2006128193	A2	11/2006
WO	2007053243	A2	5/2007
WO	2007071436	A2	6/2007
WO	2007081820	A1	7/2007
WO	2008005405	A2	1/2008
WO	2008035337	A2	3/2008
WO	2008070797	A2	6/2008
WO	2008100600	A1	8/2008
WO	2008147964	A1	12/2008
WO	2008150529	A1	12/2008
WO	2009024859	A2	2/2009
WO	2009042196	A2	4/2009
WO	2009045338	A1	4/2009
WO	2009053497	A1	4/2009
WO	2009061389	A2	5/2009
WO	2009149462	A2	12/2009
WO	2010008548	A2	1/2010
WO	2010008549	A1	1/2010
WO	2010037141	A1	4/2010
WO	2010096176	A1	8/2010
WO	2010098857	A1	9/2010
WO	2010141847	A1	12/2010
WO	2011057087	A1	5/2011
WO	2012032187	A1	3/2012
WO	2012161786	A1	11/2012
WO	2002043620	A1	6/2022

OTHER PUBLICATIONS

Al Zaibag, Muayed, et al., "Percutaneous Balloon Valvotomy in Tricuspid Stenosis," British Heart Journal, Jan. 1987, vol. 57, No. 1,pp. 51-53.

Al-Khaja, N., et al., "Eleven Years' Experience with Carpentier-Edwards Biological Valves in Relation to Survival and complications," European Journal of Cardiothoracic Surgery 3:305-311, Jun. 30, 2009.

Almagor, Y. et al., "Balloon Expandable Stent Implantation in Stenotic Right Heart Valved Conduits," Journal of the American College of Cardiology, Nov. 1, 1990, 16(6):1310-1314.

Andersen HR, Knudsen LL, Hasenkam JM. Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs. European heart Journal. May 1, 1992;13(5):704-8.

Andersen, H. R., "History of Percutaneous Aortic Valve Prosthesis," Herz, Aug. 2009, 34(5):343-346.

Andersen, Henning Rud, Transluminal Catheter Implanted Prosthetic Heart Valves, International Journal of Angiology 7:102-106 (1998).

Benchimol, Alberto, et al., "Simultaneous Left Ventricular Echocardiography and Aortic Blood Velocity During Rapid Right Ventricular Pacing in Man," The American Journal of the Medical Sciences, Jan.-Feb. 1977 vol. 273, No. 1, pp. 55-62.

Braido, et al., U.S. Appl. No. 29/375,243, filed Sep. 20, 2010, titled "Surgical Stent Assembly".

Buellesfeld L. et al., "Percutaneous Implantation of the First Repositionable Aortic Valve Prosthesis in a Patient With Severe Aortic Stenosis", Catheterization and Cardiovascular Interventions, (Mar. 24, 2008), vol. 71, pp. 579-584, XP055338603.

Buellesfeld, et al., "Treatment of paravalvular leaks through inverventional techniques," Multimed Man Cardiothorac Surg., Department of Cardiology, Ben University Hospital, pp. 1-8, Jan. 2011.

Curriculum Vitae of Robert A. Ersek, M.D., Facs, Jul. 10, 2009, http://www.ersek.com/rae-cv.htm.

De Cicco, et al., "Aortic Valve Periprosthetic Leakage: Anatomic Observations and Surgical Results", The Annals of Thoracic Surgery, vol. 79, No. 5, May 2005, pp. 1480-1485.

Dewey, et al., "Transapical Aortic Valve Implantation: An Animal Feasibility Study", The Annals of Thoracic Surgery, vol. 82, No. 1, Jul. 2006, pp. 110-116.

Dotter, M.D., Charles T., "Transluminal Treatment of Arteriosclerotic Obstruction," University of Oregon's Minthorn Memorial Laboratory for Cardiovascular Research through Radiology, Circulation, vol. XXX, Nov. 1964, pp. 654-670.

E. Grube et al., "Percutaneous Implantation of the CoreValve Self-Expanding Valve Prothesis in High-Risk Patients With Aortic Valve Disease. The Siegburg First-in-Man Study", Circulation, (20060000), vol. 114, pp. 1616-1624, XP055342562.

European Communication for Application No. 09788918.2 dated Jun. 29, 2015.

Evidence—Anlage 3 (Photograph).

Extended European Search Report for Application No. 14180622.4 dated Nov. 21, 2014.

Extended European Search Report for Application No. 14180623.2 dated Nov. 24, 2014.

Extended European Search Report for Application No. 14180625.7 dated Nov. 24, 2014.

Gossl et al., "Percutaneous Treatment of Aortic and Mitral Valve Paravalvular Regurgitation", Current Cardiology Reports, vol. 15, No. 8, Aug. 2013, pp. 1-8.

Heat Advisor, "Heart Repairs Without Surgery: Minimally Invasive Procedures Aim to Correct Valve Leakage", Technology Frontier, Sep. 2004, pp. 4-5.

Hijazi et al., Transcatheter Valve Repair, CRC Press, Jan. 2006, pp. 165-186.

Hourihan, et al., "Transcatheter Umbrella Closure of Valvular and Paravalvular Leaks," Journal of the American College of Cardiology, vol. 20, No. 6, pp. 1371-1377, Nov. 1992.

Huber, et al., "Direct-Access Valve Replacement: A Novel Approach for Off-Pump Valve Implantation Using Valved Stents", Journal of the American College of Cardiology, vol. 46, No. 2, Jul. 2005, pp. 366-370.

Inoune, M.D., Kanji et al., "Clinical Application of Transvenous Mitral Commissurotomy by a New Balloon Catheter," The Journal of Thoracic and Cardiovascular Surgery 87:394-402, 1984.

International Search Report and Written Opinion PCT/US2014/020872 dated Mar. 19, 2014.

International Search Report and Written Opinion PCT/US2014/020872 dated May 19, 2014.

International Search Report from corresponding PCT application No. PCT/US2011/054973 dated Apr. 23, 2012.

International Search Report PCT/US2009/004094 dated Mar. 3, 2010.

Knudsen LL, Andersen HR, Hasenkam JM. Catheter-Implanted Prosthetic Heart Valves: Transluminal catheter implantation of a new expandable artificial heart valve in the descending thoracic aorta in isolated vessels and closed chest pigs. The International Journal of Artificial Organs. May 1993; 16(5):253-62.

Kolata, Gina, "Device That Opens Clogged Arteries Gets a Failing Grade in a New Study," nytimes.com, http://www.iytimes.com/1991/01/03/health/device-that-opens-clogged-arteri- es-gets-a-faili . . . , Jul. 29, 2009, 2 pages.

Lawrence, Jr., M.D., David D., "Percutaneous Endovascular Graft: Experimental Evaluation," Radiology 1897; 163: 357-360.

(56) **References Cited**

OTHER PUBLICATIONS

M.J. Mack, "Minimally invasive cardiac surgery", Surgical Endoscopy, 20:S488-S492, DOI: 10.1007/s00464-006-0110-8 Presented Mar. 23, 2006.
Merriam Webster definition of "retard," www.merriam-webster.com/dictionary/retard, printed Jun. 13, 2016.
Merriam Webster definition of "prevent," www.merriam-webstercom/dictionary/prevent.
Moazami et al., "Transluminal Aortic Valve Placement: A Feasibility Study With a Newly designed Collapsible Aortic Valve.", ASAIO Journal, (19960900), vol. 42, pp. M381-M385, XP000683605.
Pavcnik, M.D., Ph.D., Dusan, et al. "Development and Initial Experimental Evaluation of a Prosthetic Aortic Valve for Transcatheter Placement," Cardiovascular Radiology 1992; 183:151-154.
Porstmann, W., et al., "Der Verschlu.beta. des Ductus Arteriosus Persistens ohne Thorakotomie," Thoraxchirurgie Vaskulare Chirurgie, Band 15, Heft 2, Stuttgart, im Apr. 1967, pp. 199-203, English translation of Abstract only.
Quaden et al., "Percutaneous aortic valve replacement: resection before implantation", European J. of Cardio-thoracic Surgery, vol. 27, Issue 5, pp. 836-840, May 2005.
Rashkind, M.D., William J., "Creationof an Atrial Septal Defect Withoput Thoracotomy," the Journal of the American Medical Association, vol. 196, No. 11, Jun. 13, 1966, pp. 173-174.
Rashkind, W. J., "Historical Aspects of Interventional Cardiology: Past, Present, Future," Texas Heart Institute Journal, Dec. 1986, 13(4):363-367.
Rodriguez et al., "Guidance of Treatment of Pehvalvular Prosthetic Leaks", Current Cardiology Reports, vol. 16, No. 1, Nov. 2013, pp. 1-6.
Rohde, et al., "Resection of Calcified Aortic Heart Leaflets In Vitro by Q-Switched 2 pm Microsecond Laser Radiation", Journal of Cardiac Surgery, 30(2): 157-62. Feb. 2015.
Rosch, M.D., Josef, "The Birth, Early Years and Future of Interventional Radiology," J Vasc Intery Radiol 2003; 14:841-853.
Ross, F.R.C.S., D.N., "Aortic Valve Surgery," Guy's Hospital, London, pp. 192-197, Jan. 1968.
Ruiz, Carlos, "Overview of PRE-CE Mark Transcatheter Aortic Valve Technologies", Euro PCR, May 25, 2010.
Sabbah, A. N. et al., "Mechanical Factors in the Degeneration of Porcine Bioprosthetic Valves: An Overview," Dec. 1989, Journal of Cardiac Surgery, 4(4):302-309.
Samuel V. Lichtenstein et al., Transapical Transcatheter Aortic Valve Implantation in Humans, Circulation, Jul. 2006, pp. 591-596, vol. 114.
Samuel V. Lichtenstein, "Closed heart surgery: Back to the future", The Journal of Thoracic and Cardiovascular Surgery, vol. 131, No. 5, pp. 941-943, May 2006.
Selby, M.D., J. Bayne, "Experience with New Retrieval Forceps for Foreign Body Removal in the Vascular, Urinary, and Biliary Systems," Radiology 1990; 176:535-538.
Serruys, P. W., et al., "Stenting of Coronary Arteries. Are we the Sorcerer's Apprentice?," European Heart Journal (1989) 10, 774-782, pp. 37-45, Jun. 13, 1989.
Sigwart, U., "An Overview of Intravascular Stents: Old and New," Chapter 48, Interventional Cardiology, 2nd Edition, W.B. Saunders Company, Philadelphia, PA, © 1994, 1990, pp. 803-815.
Swiatkiewicz, et al., "Percutaneous closure of mitral perivalvular leak," Kardiologia Polska, vol. 67, No. 7, pp. 762-764, Jul. 2009.
Th. Walther et al., "Transapical Approach for Sutureless Stent-Fixed Aortic Valve Implantation: Experimental Results", European Journal of Cardio-Thoracic Surgery, vol. 29, No. 5, May 2006, pp. 703-708.
U.S. Appl. No. 13/572,842, filed Aug. 13, 2012, Kovalsky.
U.S. Appl. No. 29/375,260, filed Sep. 20, 2010.
Uchida, Barry T., et al., "Modifications of Gianturco Expandable Wire Stents," AJR: 150, May 1988, Dec. 3, 1987, pp. 1185-1187.
Urban, M.D., Philip, "Coronary Artery Stenting," Editions Medecine et Hygiene, Geneve, 1991, pp. 5-47.
Watt, A.H., et al. "Intravenous Adenosine in the Treatment of Supraventricular Tachycardia; a Dose-Ranging Study and Interaction with Dipyridamole," British Journal of Clinical Pharmacology (1986), 21, 227-230.
Webb et al., "Percutaneous Aortic Valve Implantation Retrograde From the Femoral Artery", Circulation, published online Feb. 2006, pp. 842-850, vol. 113, American Heart Association, Dallas, TX, USA.
Wheatley, M.D., David J., "Valve Prostheses," Rob & Smith's Operative Surgery, Fourth Edition, pp. 415-424, Butterworths 1986.
Zegdi, Rachid, Md, PhD et al., "Is It Reasonable to Treat All Calcified Stenotic Aortic Valves With a Valved Stent?" 579-584, J. of the American College of Cardiology, vol. 51. No. 5, Feb. 5, 2008.

* cited by examiner

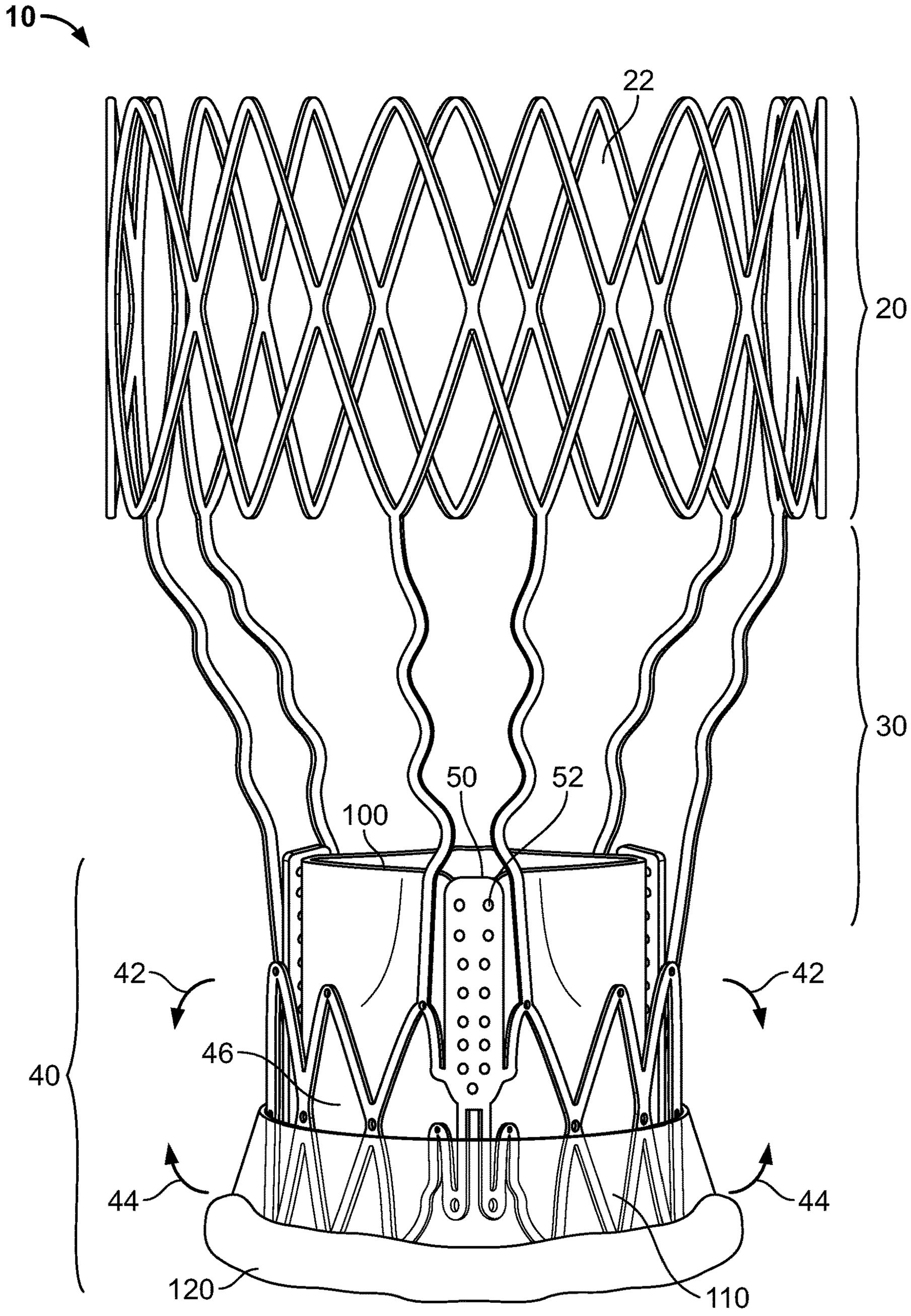
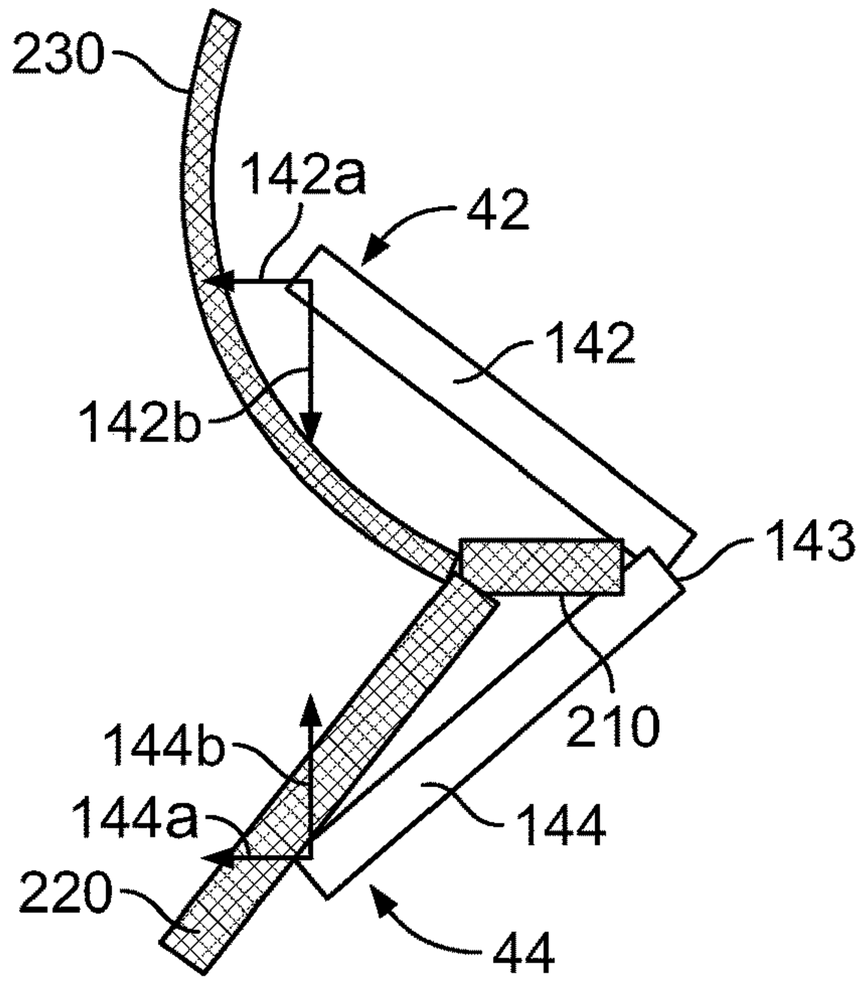


FIG. 1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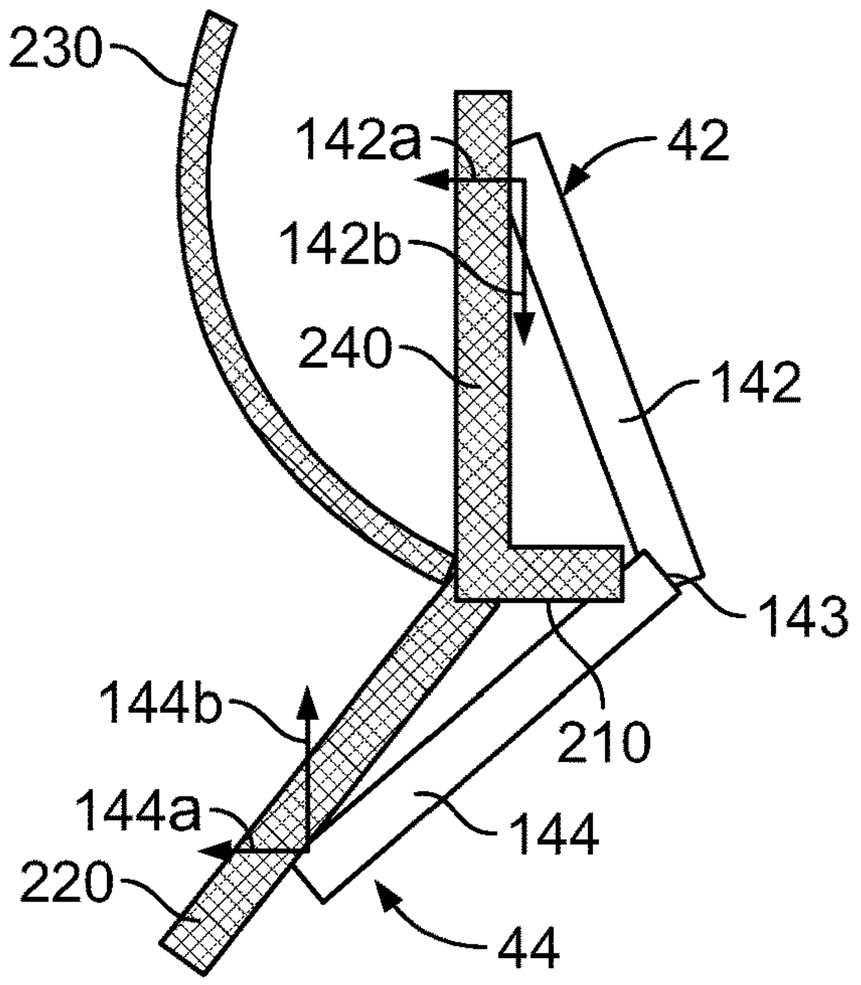
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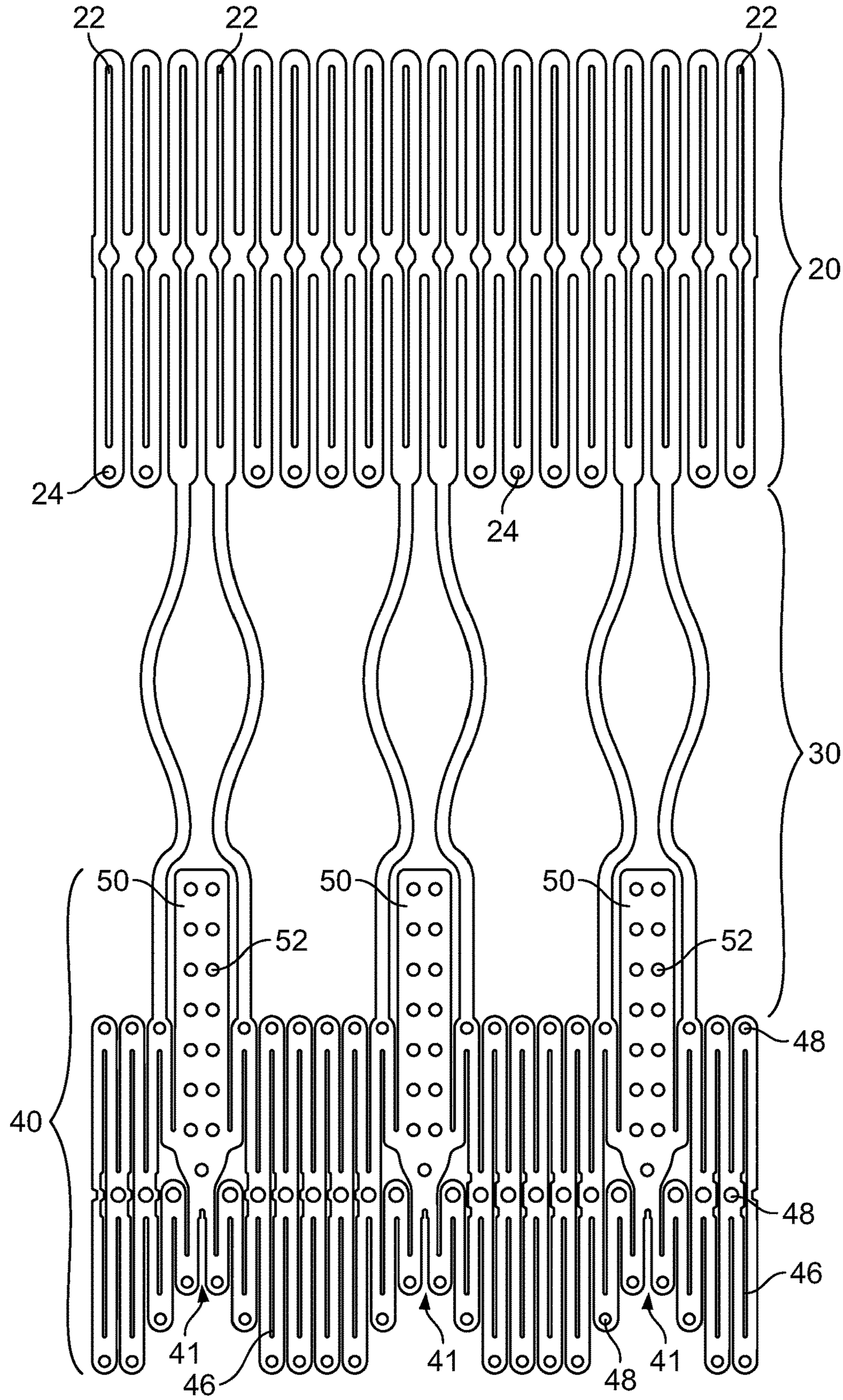
FIG. 3



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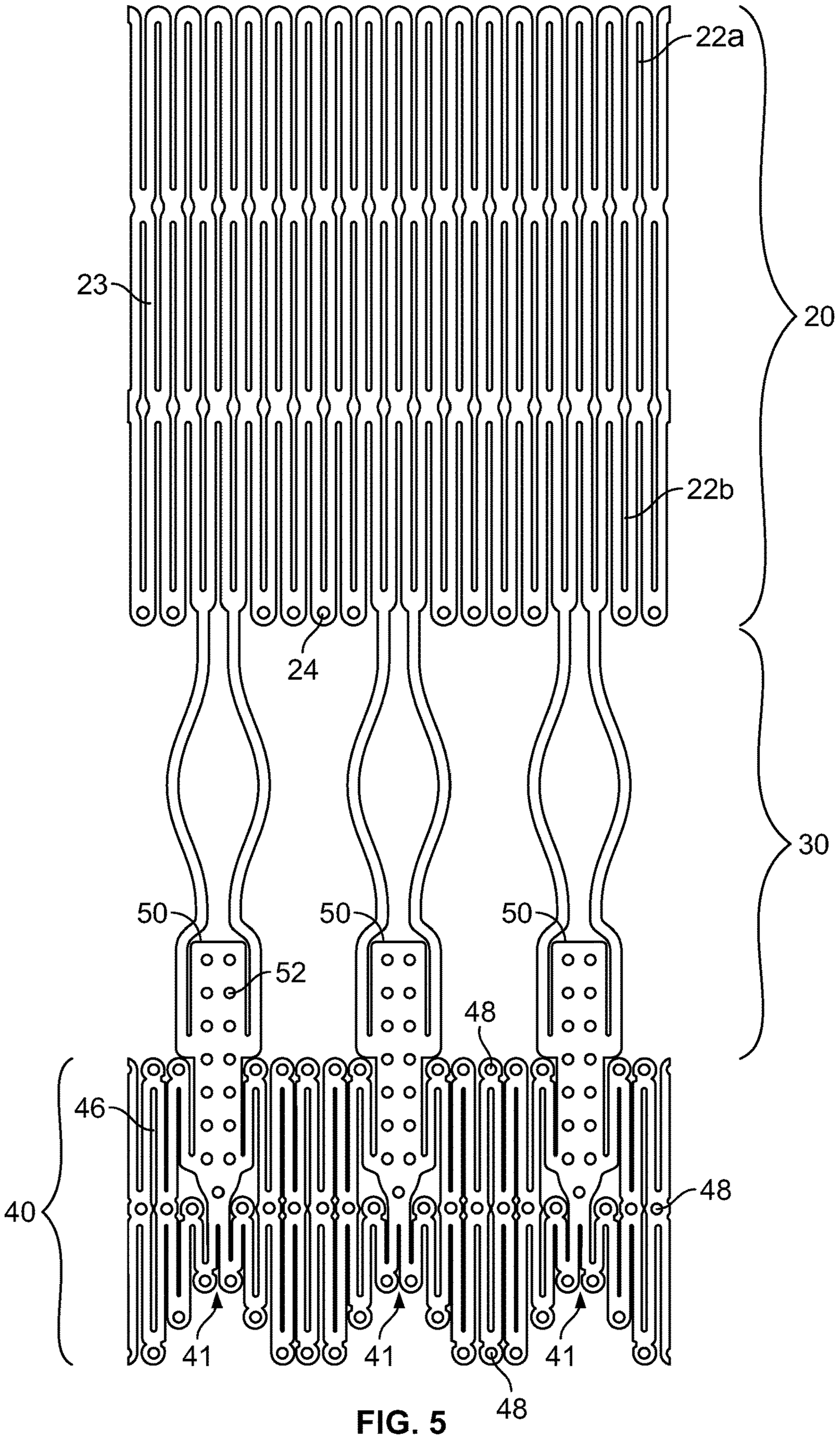

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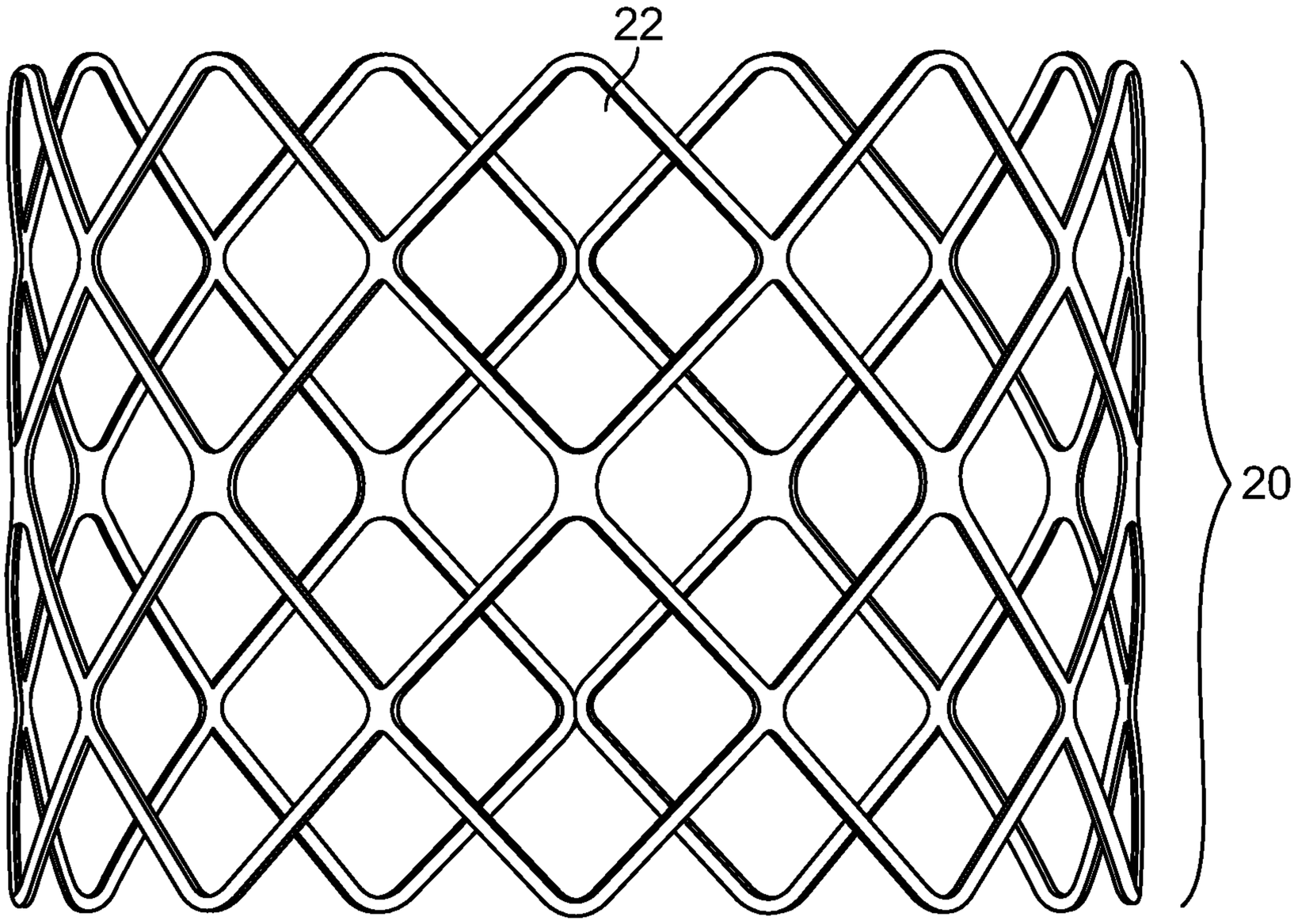

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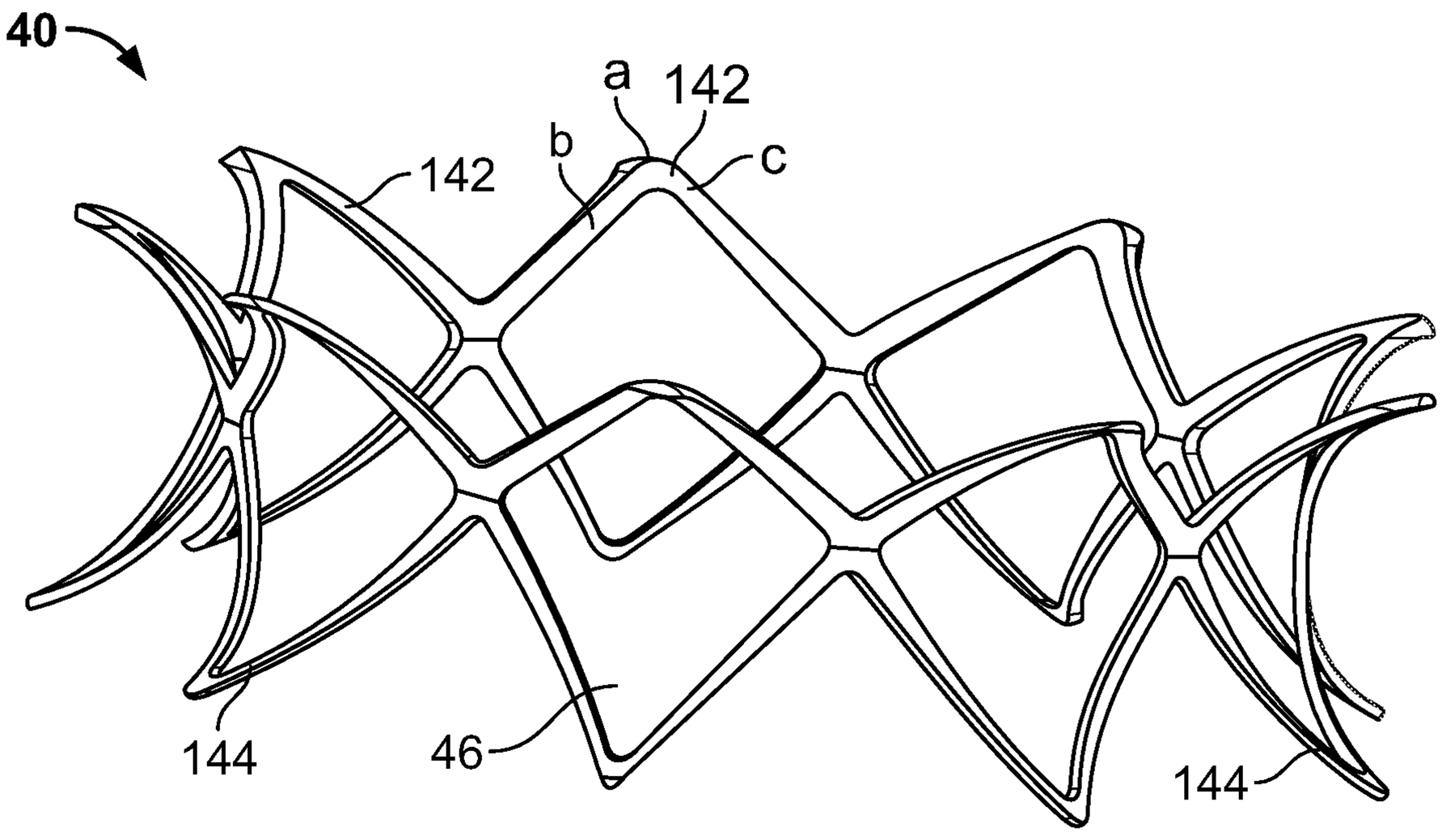


FIG. 7

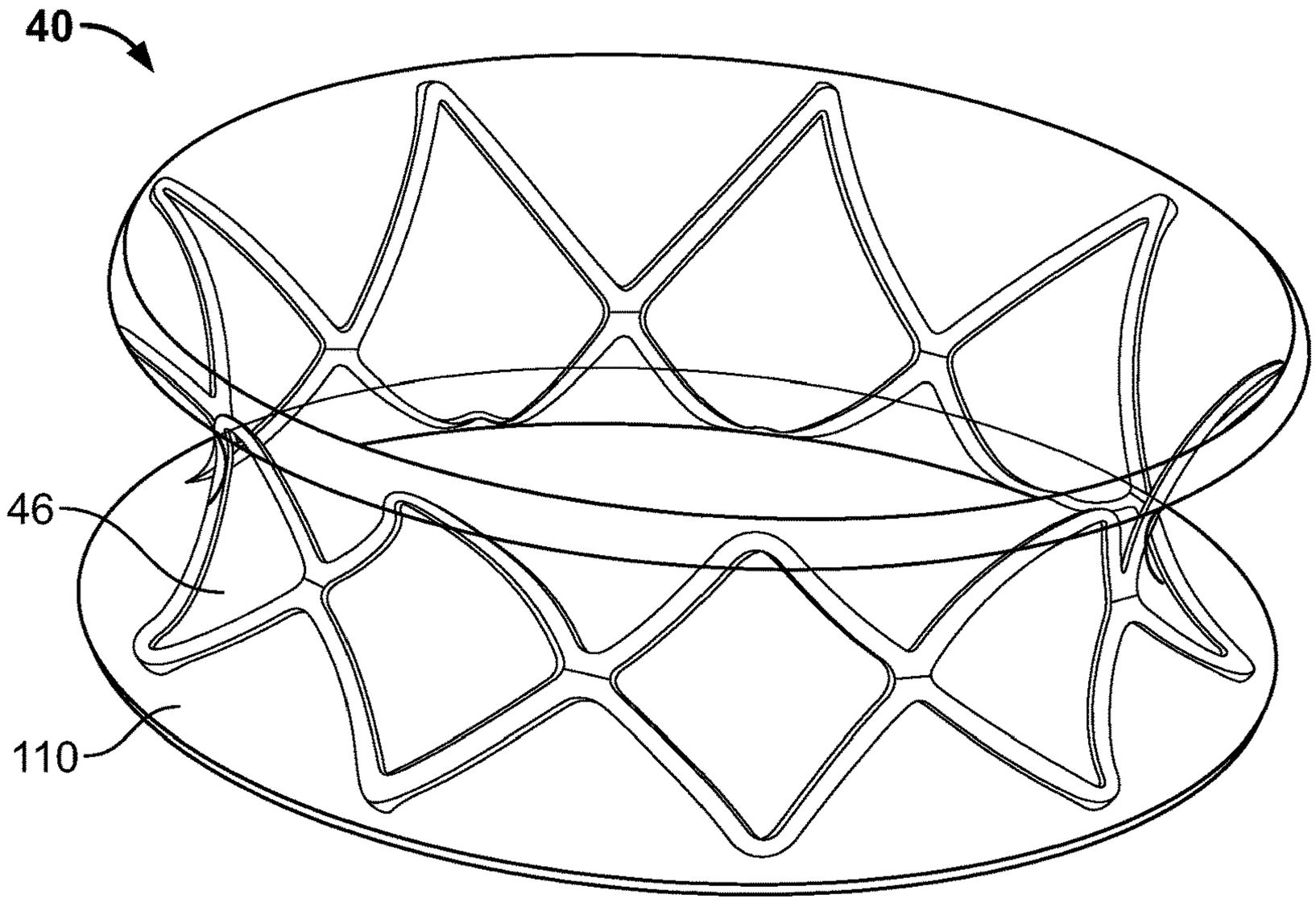
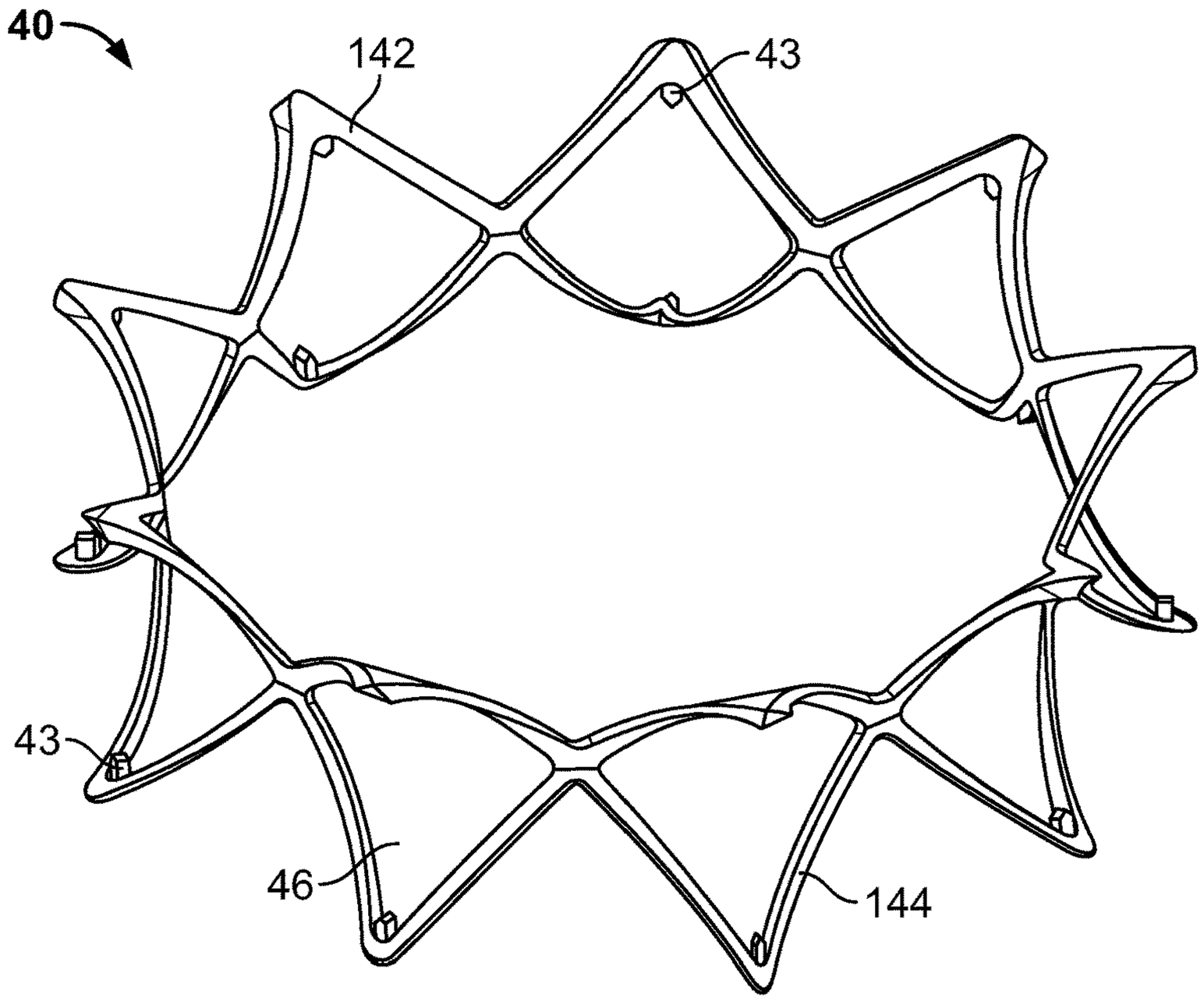


FIG. 8



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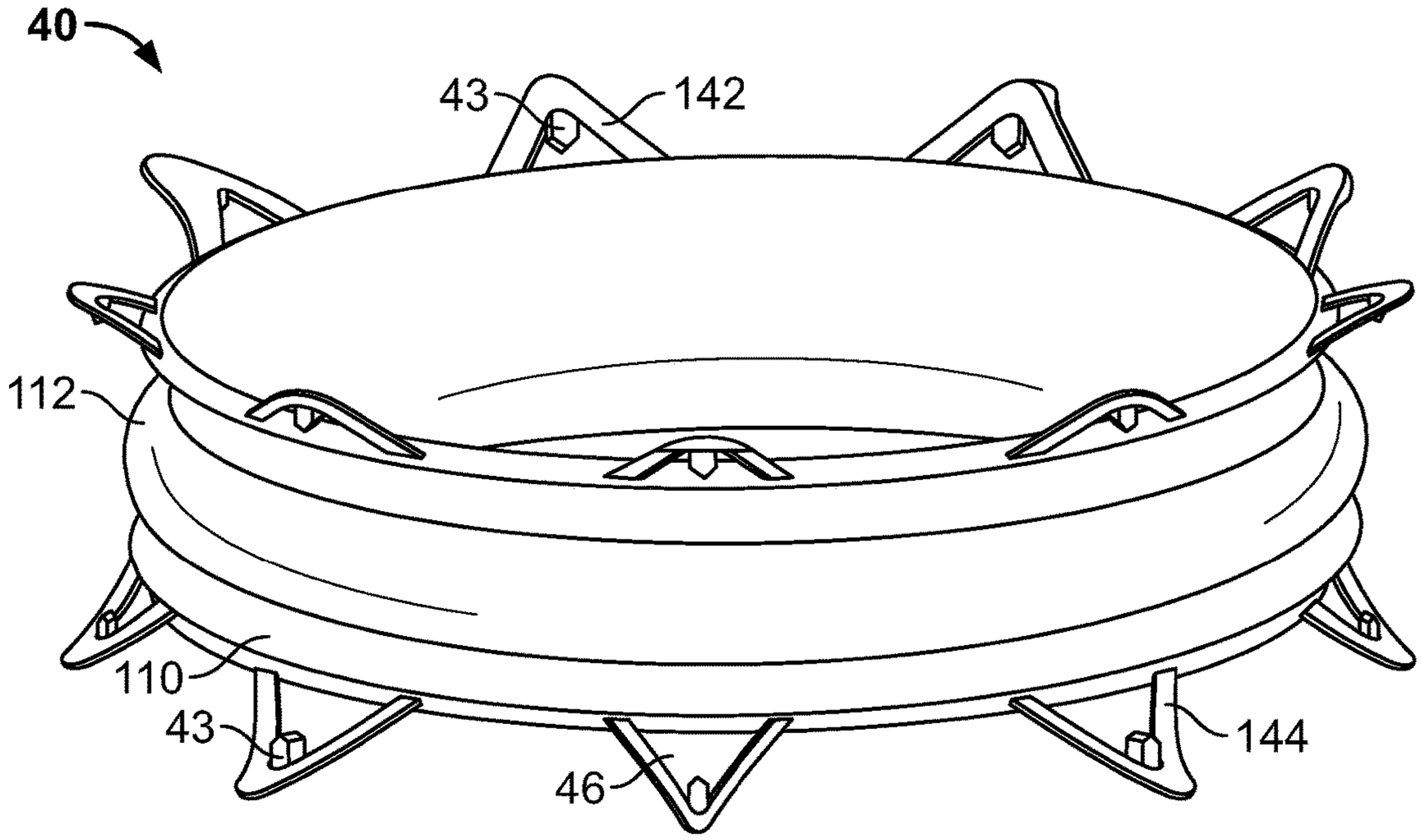

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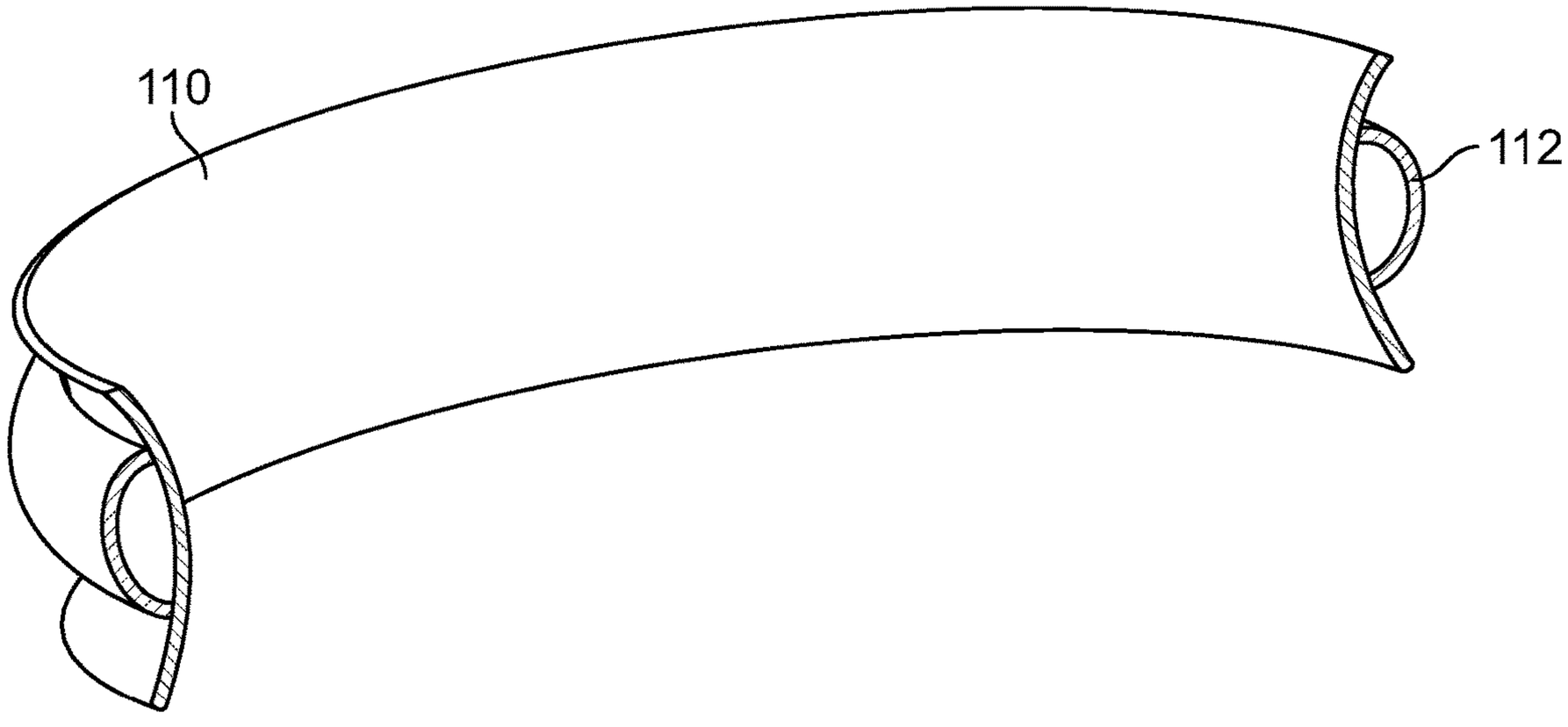
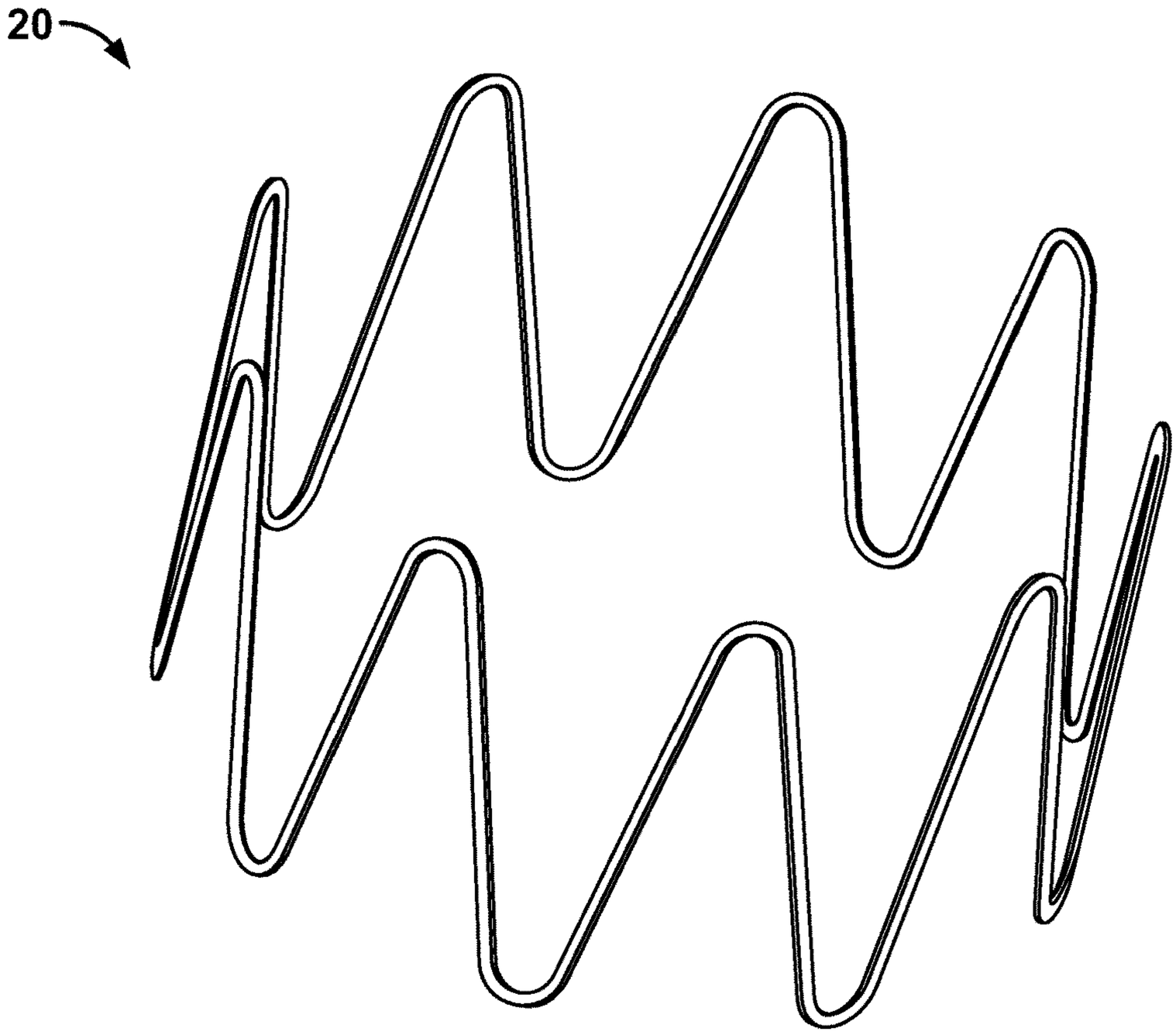


FIG. 11



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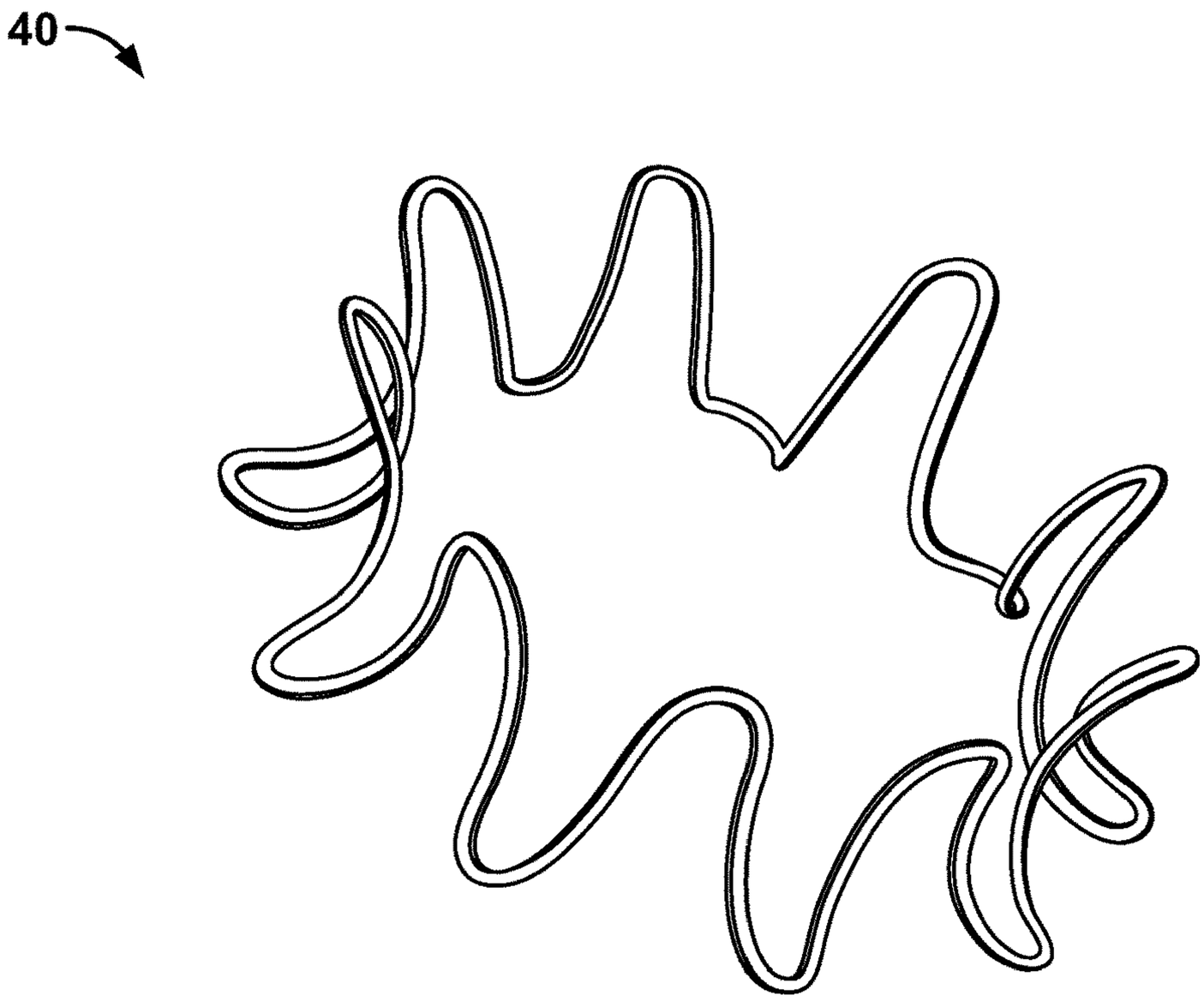

FIG. 13

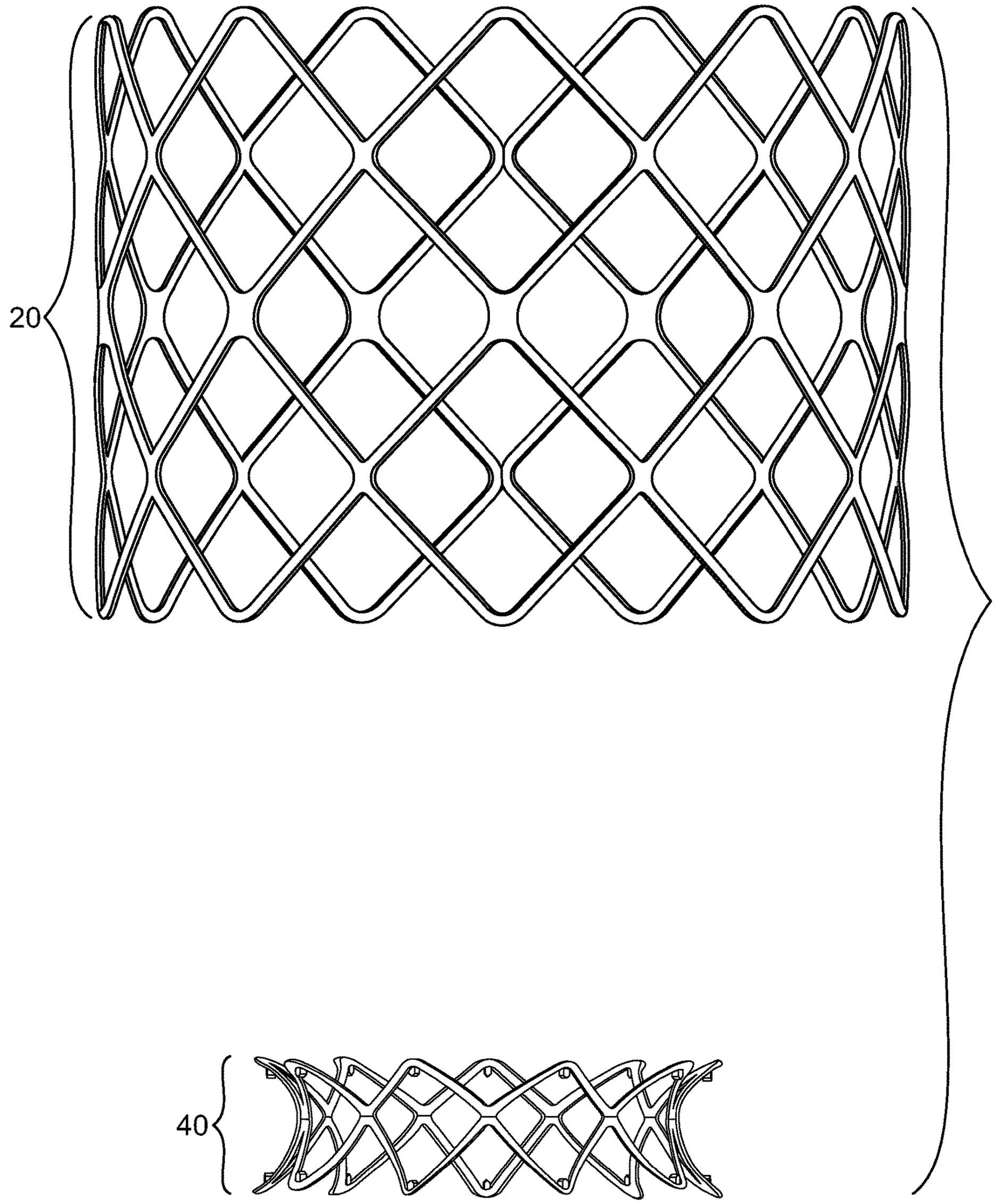

FIG. 14

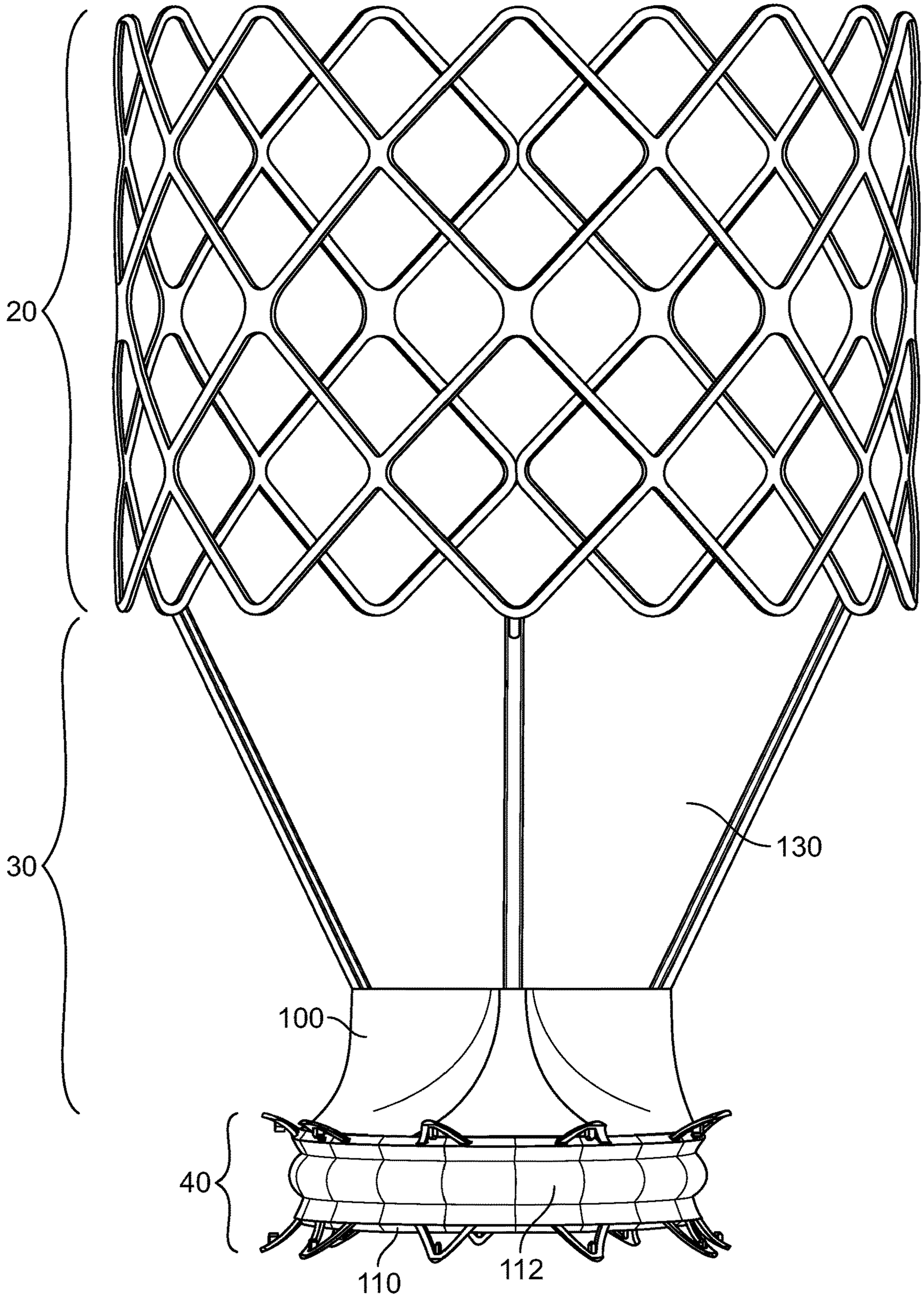

FIG. 15

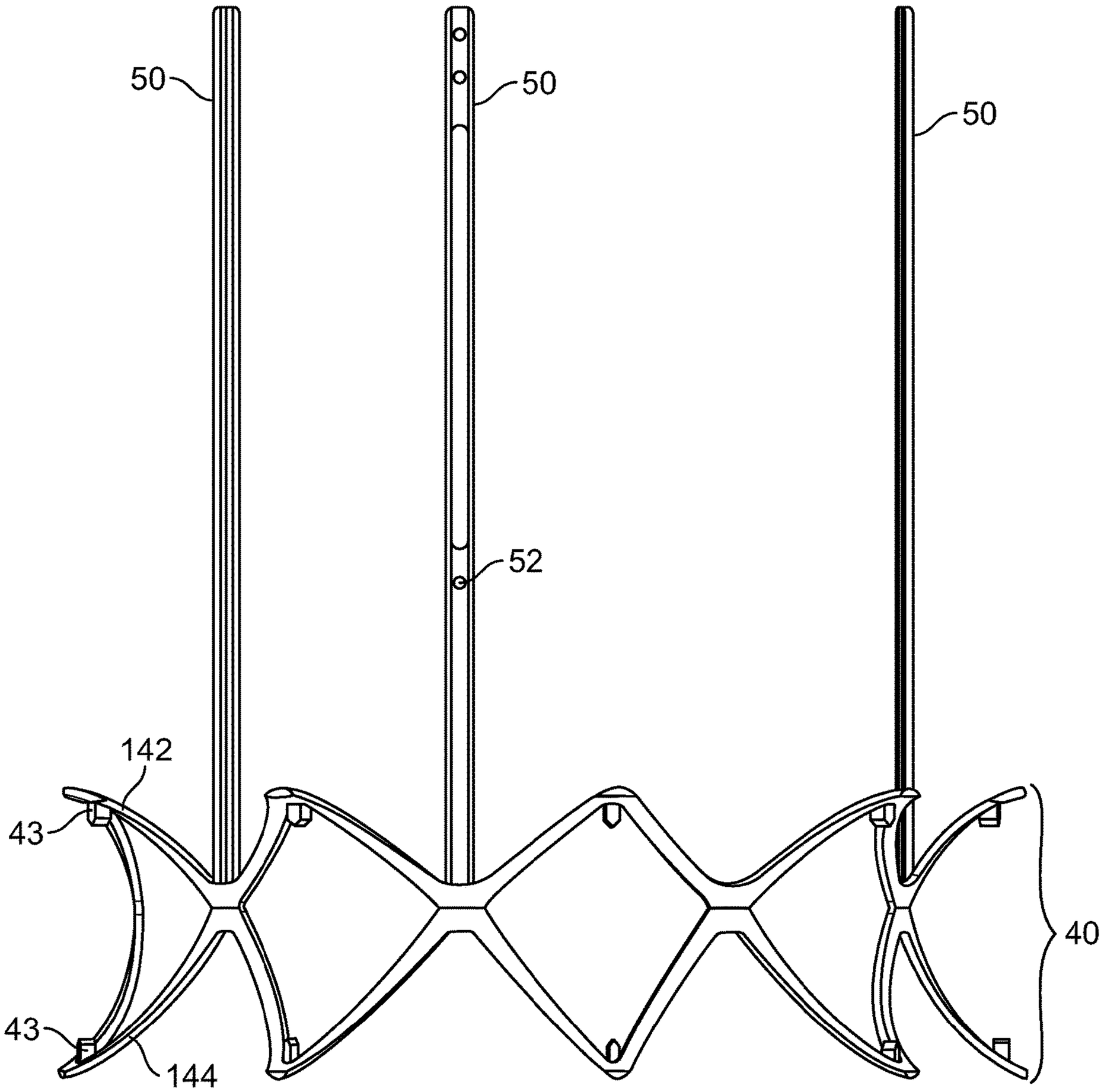

FIG. 16

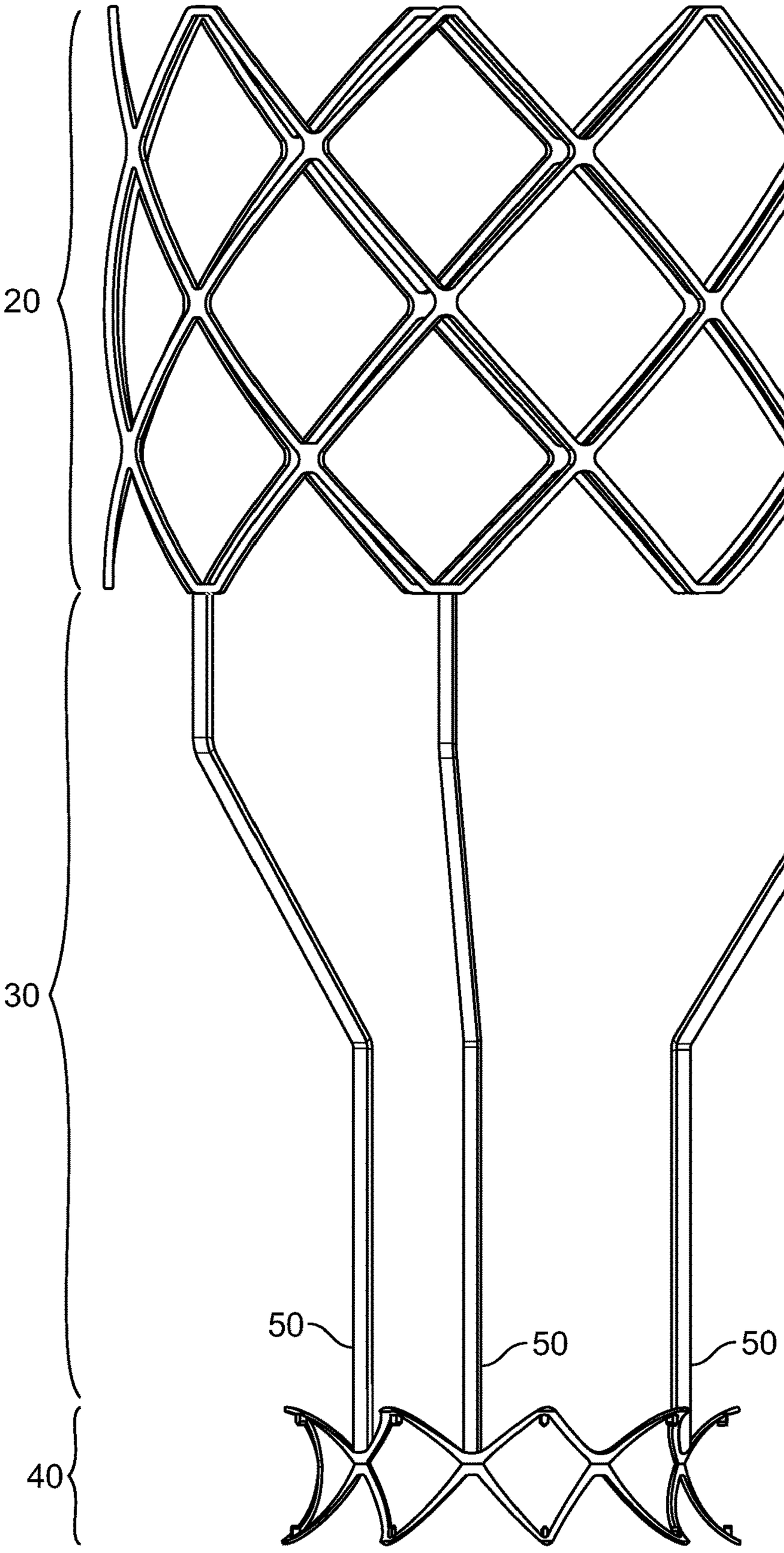

FIG. 17

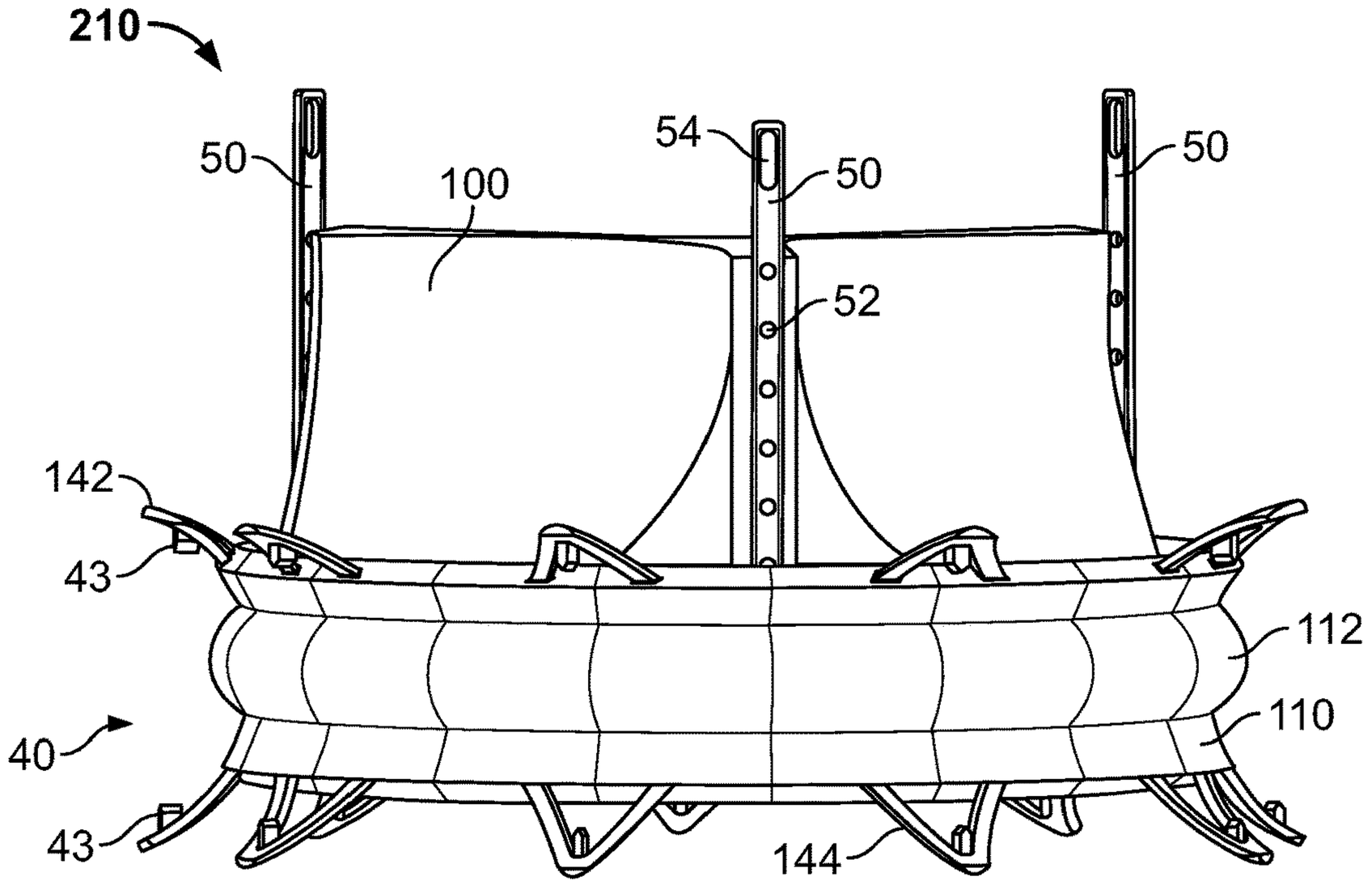
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FIG. 18

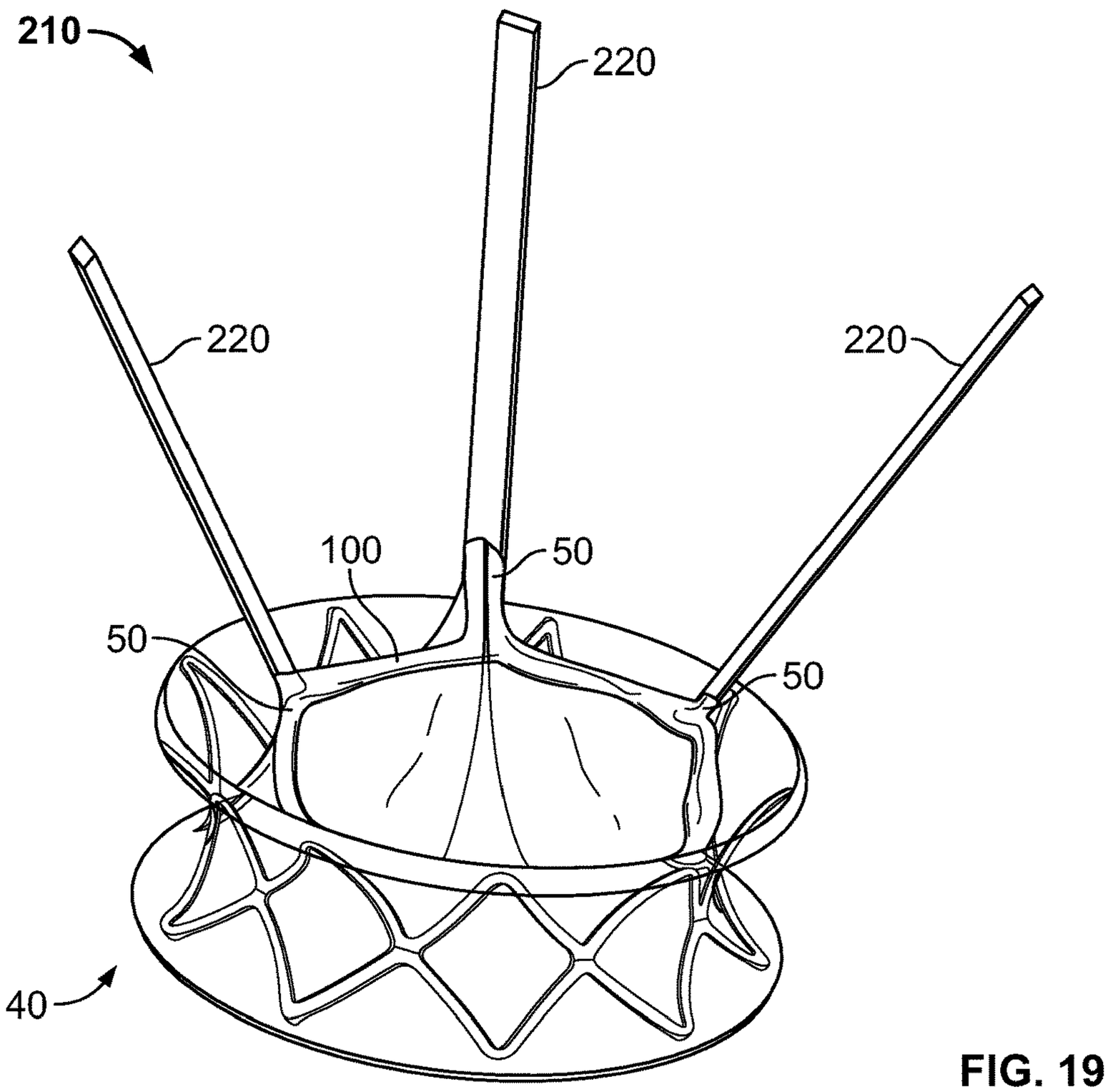
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FIG. 19

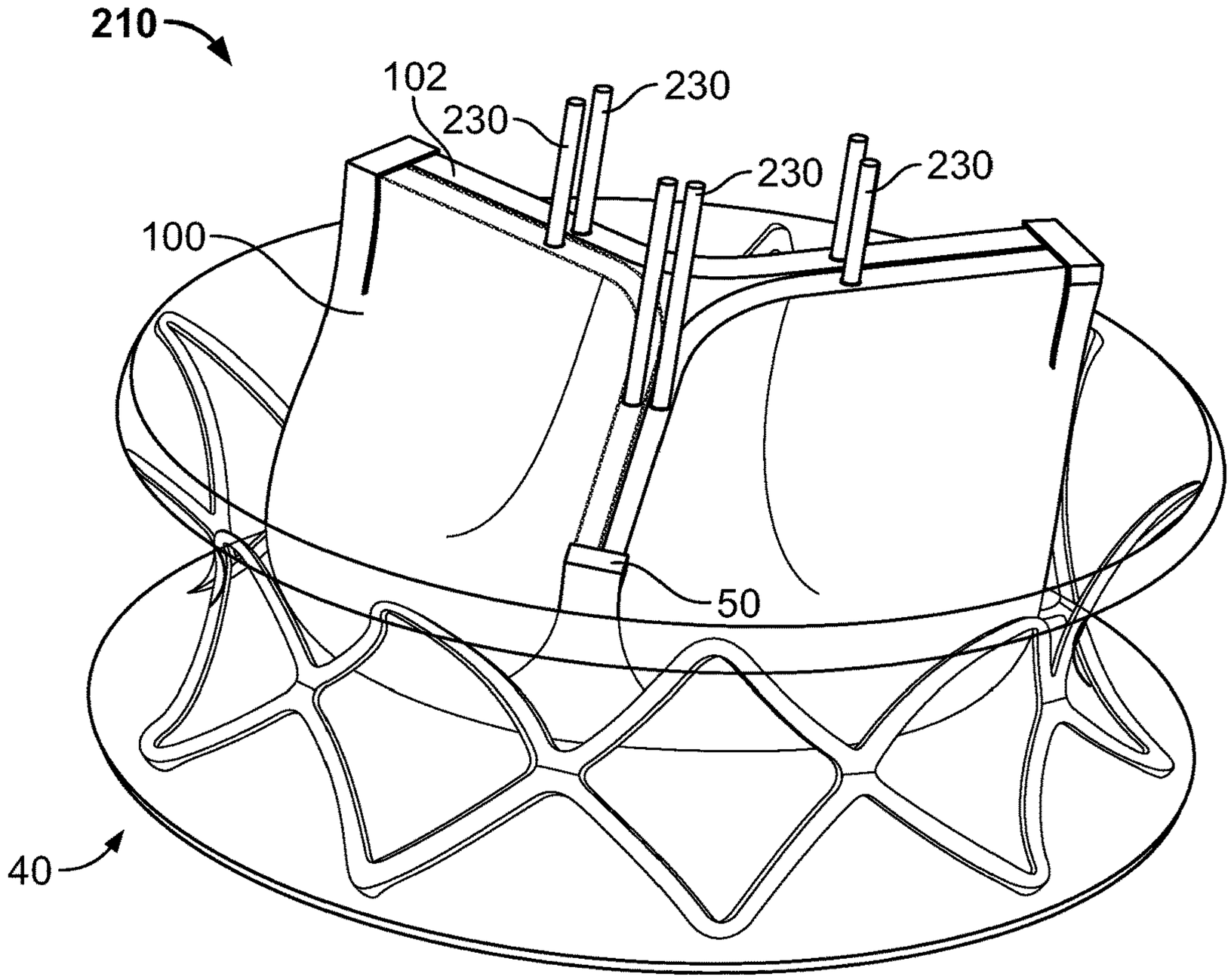

FIG. 20

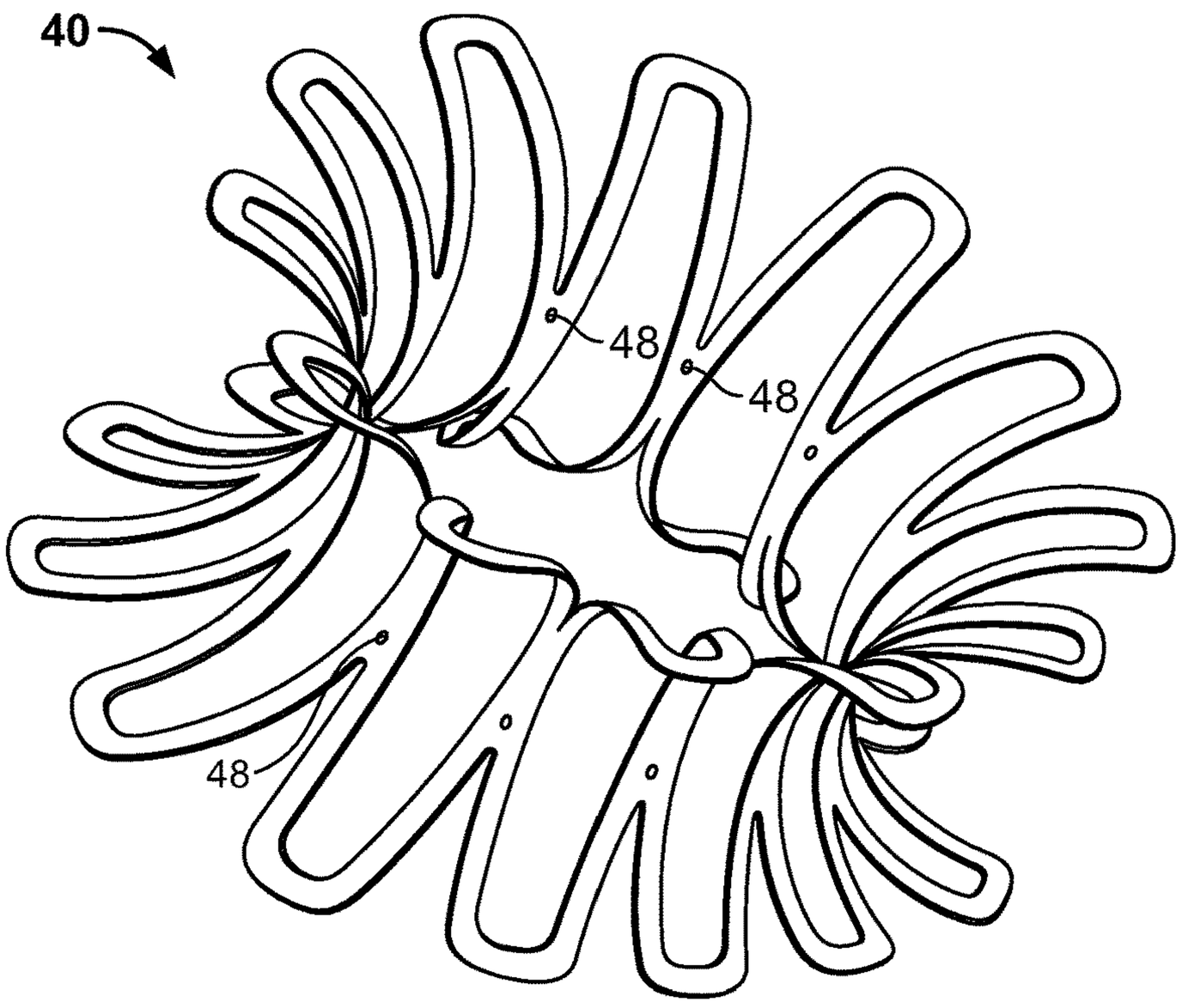

FIG. 21

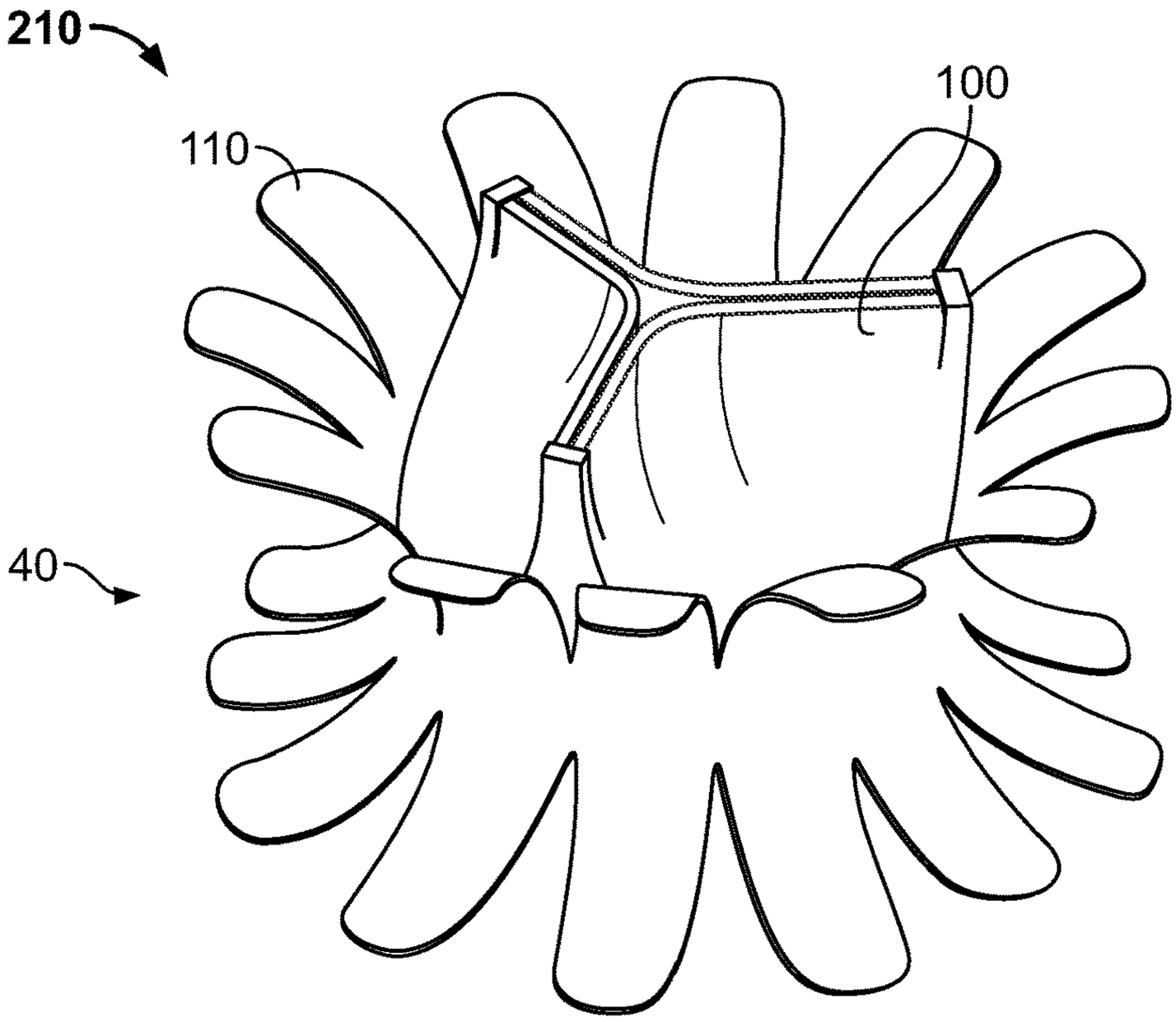

FIG. 22

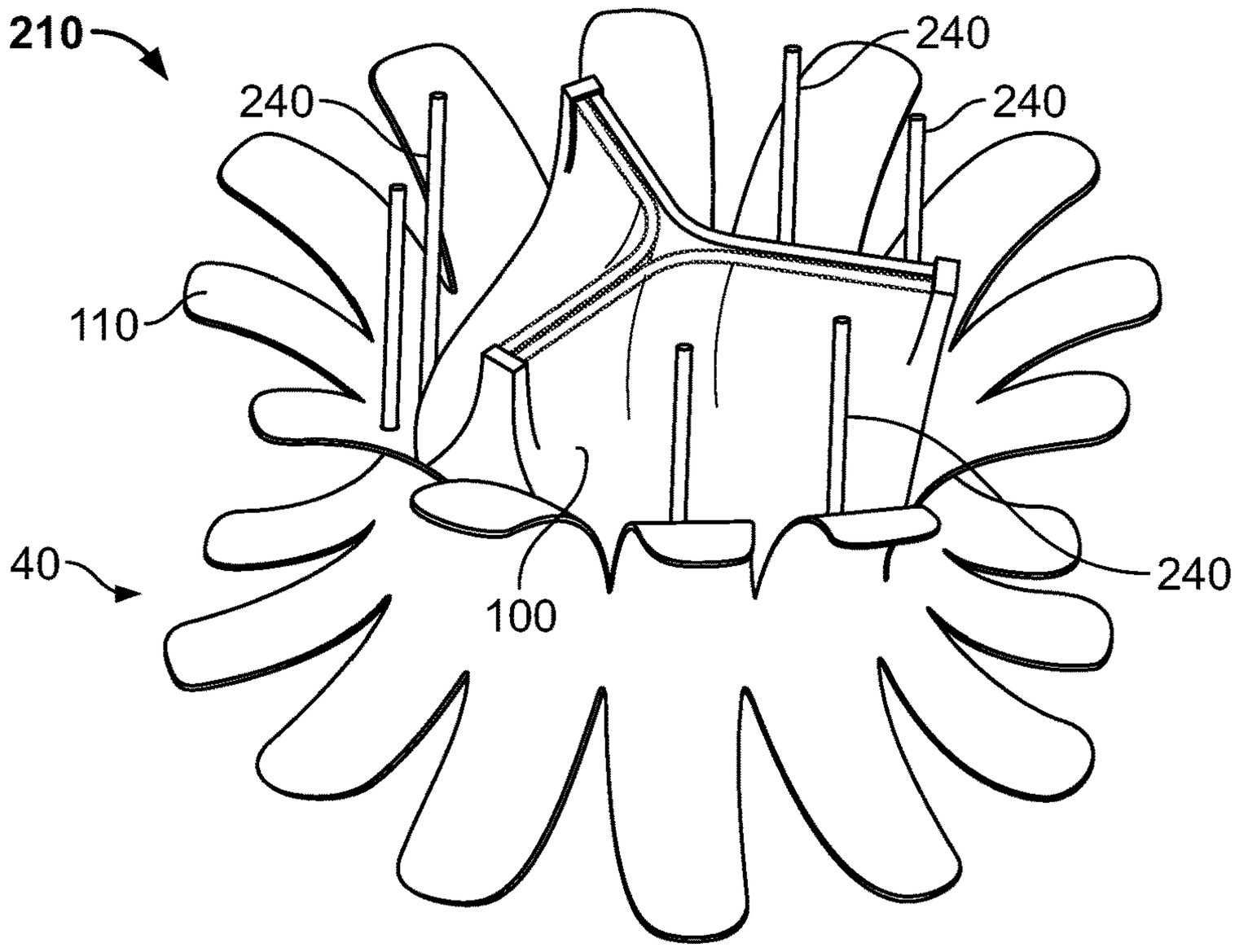

FIG. 23

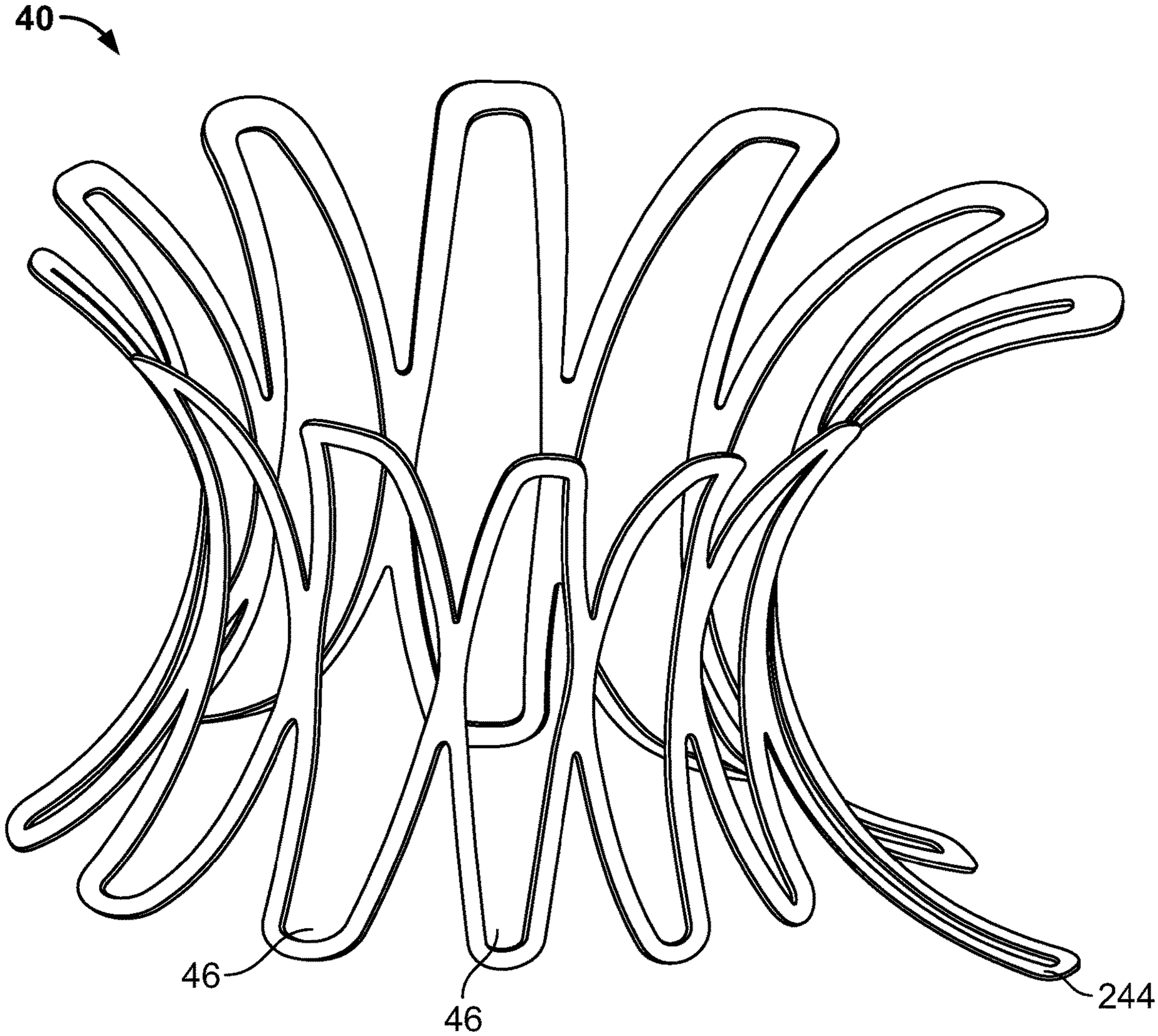

FIG. 24

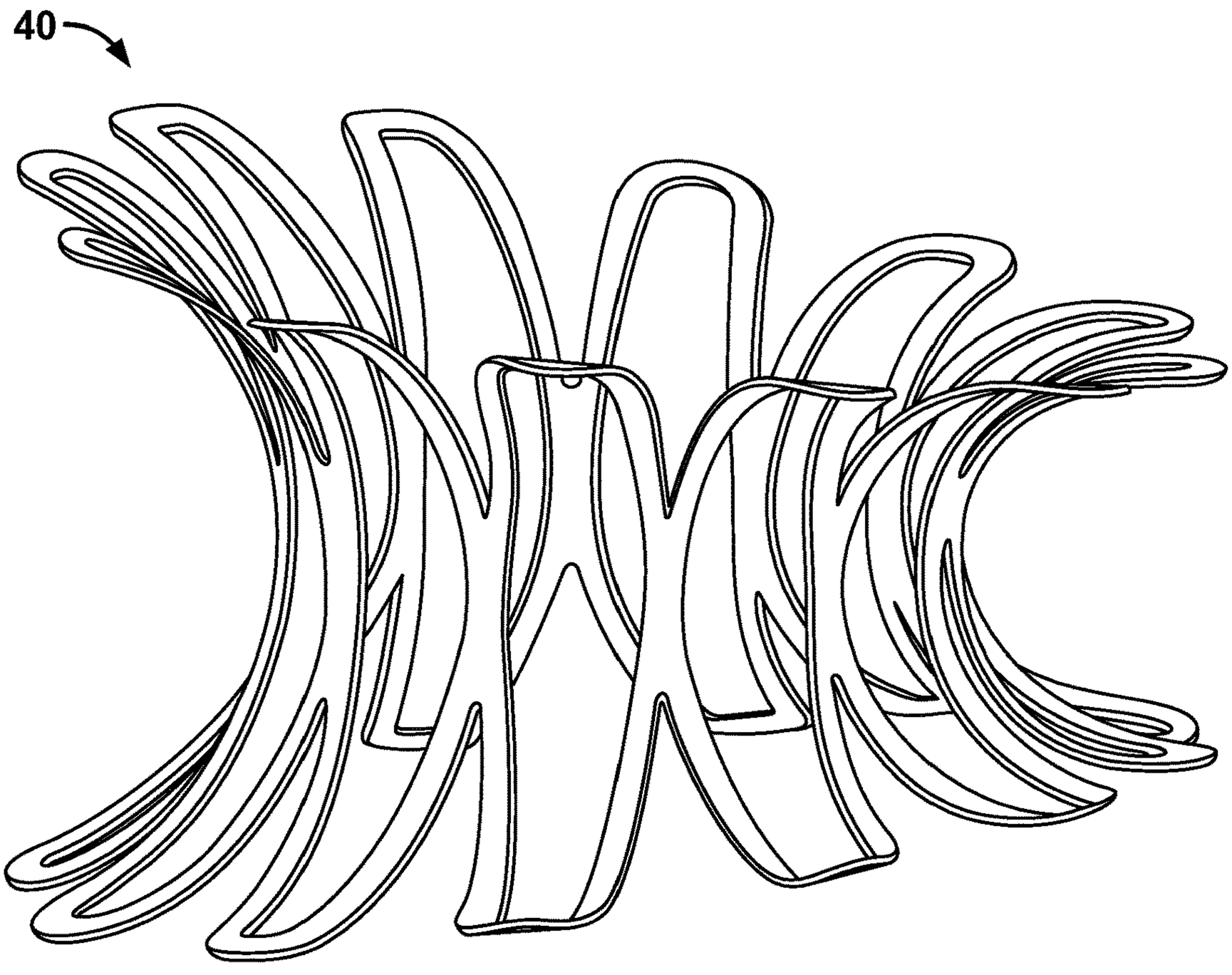

FIG. 25

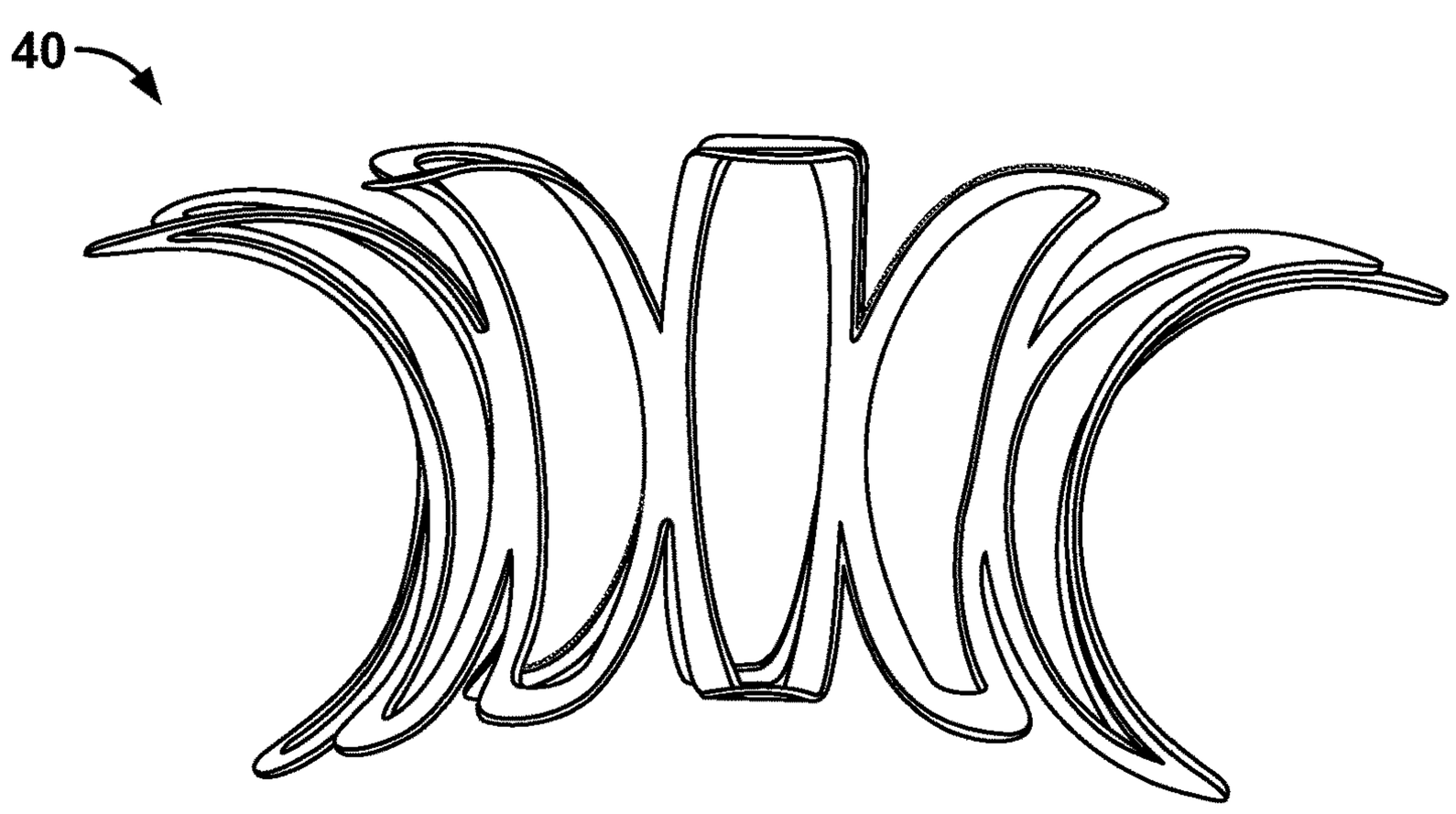

FIG. 26

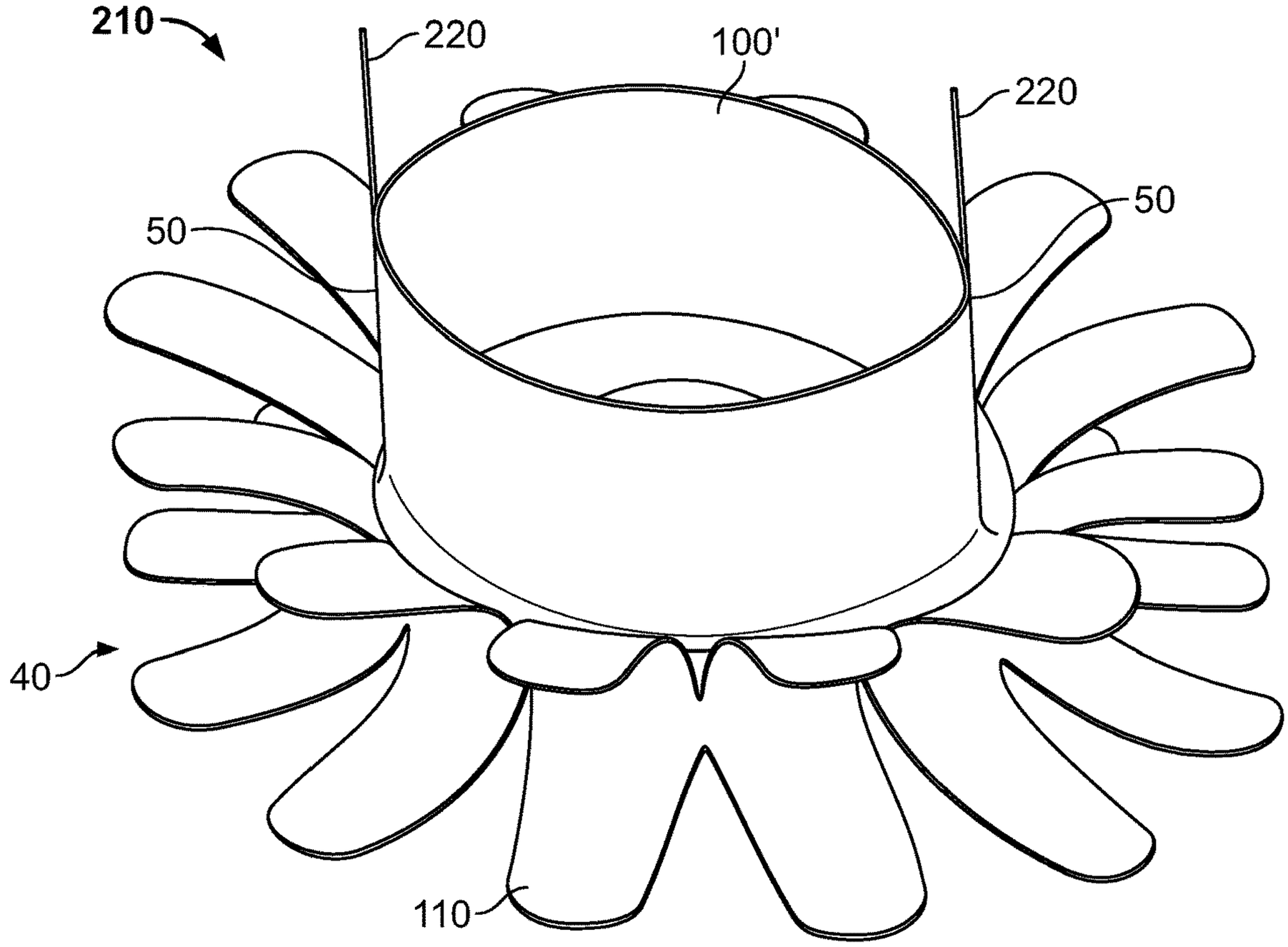

FIG. 27

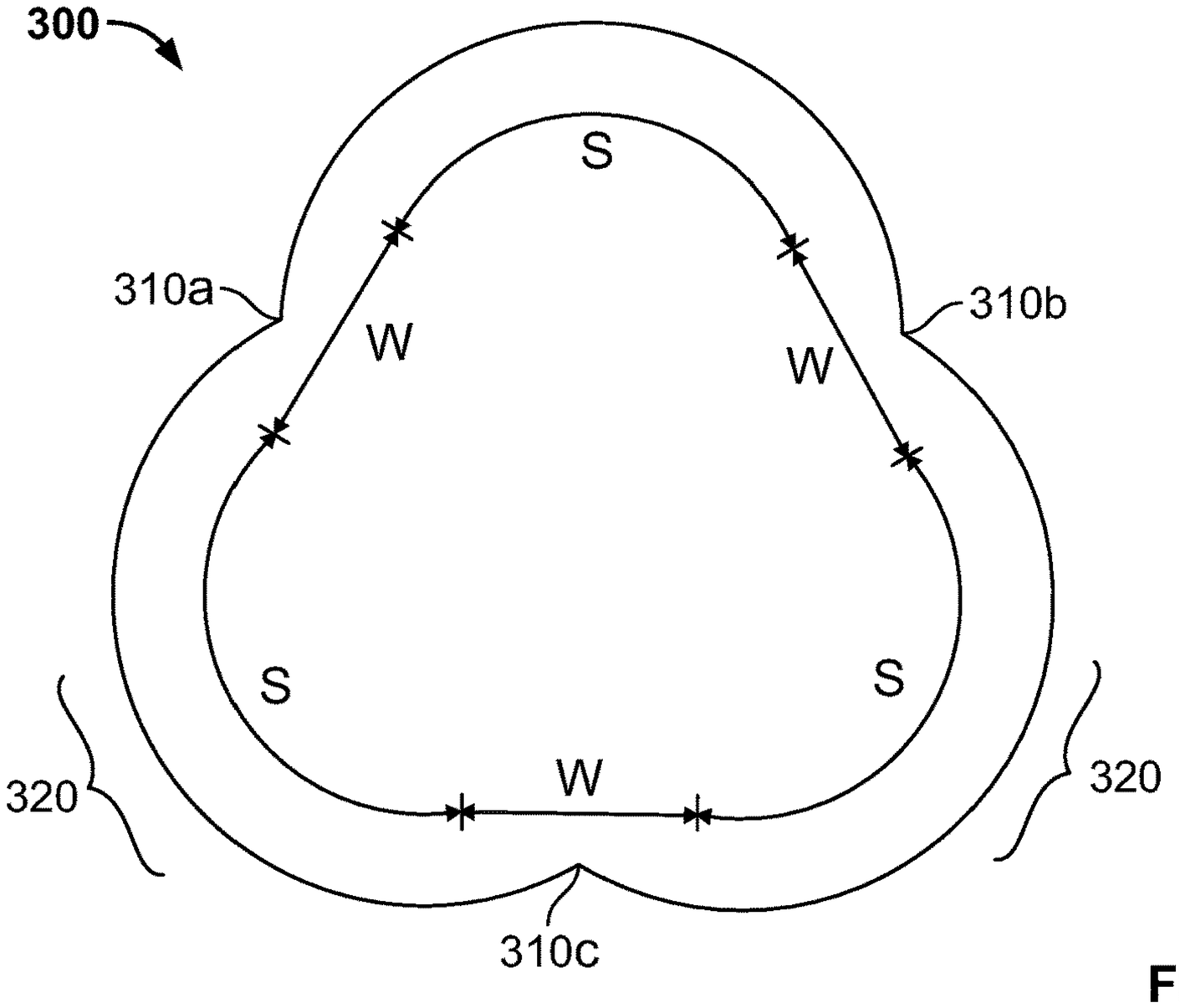

FIG. 28

COLLAPSIBLE-EXPANDABLE PROSTHETIC HEART VALVES WITH STRUCTURES FOR CLAMPING NATIVE TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 16/545,481, filed Aug. 20, 2019, which is a continuation of U.S. patent application Ser. No. 14/688,357, filed Apr. 16, 2015, now U.S. Pat. No. 10,426,604, which is a continuation of U.S. patent application Ser. No. 11/906,133, filed Sep. 28, 2007, now U.S. Pat. No. 9,532,868, the disclosures of which are hereby incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates to prosthetic heart valves, and more particularly to prosthetic heart valves that can be collapsed to a relatively small size for delivery into a patient and then re-expanded to full operating size at the final implant site in the patient.

At present there is considerable interest in prosthetic heart valves that can be collapsed to a relatively small circumferential (or annular perimeter) size for delivery into a patient (e.g., through tubular delivery apparatus like a catheter, a trocar, laparoscopic instrumentation, or the like). This is of interest because it can help to make replacement of a patient's defective heart valve less invasive for the patient. When the prosthetic valve reaches the desired implant site in the patient, the valve is re-expanded to a larger circumferential (or annular perimeter) size, which is the full operating size of the valve.

Because of the interest in prosthetic heart valves of the above general type, improvements to valves of this type are always being sought.

BRIEF SUMMARY OF THE INVENTION

In accordance with certain possible aspects of the invention, a prosthetic heart valve may include an annular structure that is annularly continuous and that has an annular perimeter that is changeable in length between (1) a first relatively small length suitable for delivery of the valve into a patient with reduced invasiveness, and (2) a second relatively large length suitable for use of the annular structure to engage tissue of the patient adjacent to the patient's native valve annulus and thereby implant the valve in the patient. The valve further includes a flexible leaflet structure attached to the annular structure. The annular structure may comprise an annular array of diamond-shaped cells. Upstream apex portions of at least some of these cells may be resiliently biased to deflect radially outwardly from at least some other portions of the annular structure, and downstream apex portions of at least some of these cells may also be resiliently biased to deflect radially outwardly from at least some other portions of the annular structure. As a result, when the valve is in use in a patient, tissue of the patient adjacent to the patient's native heart valve annulus is clamped between the upstream and downstream apex portions, with the upstream apex portions engaging tissue upstream from the annulus, and with the downstream apex portions engaging tissue downstream from the annulus.

In accordance with certain other possible aspects of the invention, a prosthetic aortic heart valve may include an annular structure that is annularly continuous and that has an annular perimeter that is changeable in length between (1) a first relatively small length suitable for delivery of the valve into a patient with reduced invasiveness, and (2) a second relatively large length suitable for use of the annular structure to engage tissue of the patient adjacent to the patient's native aortic valve annulus and also downstream from ostia of the patient's coronary arteries to thereby implant the valve in the patient. The annular structure may include an annularly continuous annulus portion adapted for implanting adjacent the patient's native aortic valve annulus upstream from the ostia of the patient's coronary arteries, and an annularly continuous aortic portion adapted for implanting in the patient's aorta downstream from those ostia. The annulus portion and the aortic portion are preferably connected to one another only by a plurality of linking structures that are disposed to pass through at least a portion of the patient's valsalva sinus at locations that are spaced from the ostia of the patient's coronary arteries in a direction that extends annularly around the valsalva sinus. The valve further includes a leaflet structure that is attached to the annulus portion. The annulus portion includes first and second tissue clamping structures that are spaced from one another along an axis that passes longitudinally through the valve, each of the clamping structures being resiliently biased to extend radially outwardly from the leaflet structure, whereby, in use, tissue of the patient adjacent to the patient's native aortic valve annulus is clamped between the first and second clamping structures, with the first clamping structure engaging tissue upstream from the annulus, and with the second clamping structure engaging tissue downstream from the annulus.

In accordance with certain still other possible aspects of the invention, a prosthetic aortic heart valve includes an annular structure that is annularly continuous and that has an annular perimeter that is changeable in length between (1) a first relatively small length suitable for delivery of the valve into a patient with reduced invasiveness, and (2) a second relatively large length suitable for use of the annular structure to engage tissue of the patient adjacent to the patient's native aortic valve annulus and thereby implant the valve in the patient. The valve further includes a flexible leaflet structure attached to the annular structure. When a valve having these aspects of the invention is implanted in the patient, any non-leaflet part of the valve that is at the level of the patient's native coronary artery ostia is confined in a direction that is circumferential of the valve to areas that are adjacent to the patient's native aortic valve commissures or downstream projections of those commissures, each of said areas having an extent in the circumferential direction that is less than the distance in the circumferential direction between circumferentially adjacent ones of those areas. In addition, the annular structure includes first and second tissue clamping structures that are spaced from one another along an axis that passes longitudinally through the valve. Each of the clamping structures is resiliently biased to extend radially outwardly from the leaflet structure, whereby, in use, tissue of the patient adjacent to the patient's native aortic valve annulus is clamped between the first and second clamping structures, with the first clamping structure engaging tissue upstream from the annulus, and with the second clamping structure engaging tissue downstream from the annulus.

Further features of the invention, its nature and various advantages, will be more apparent from the accompanying drawings and the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an elevational view of some components of an illustrative prosthetic valve in accordance with the invention.

FIG. **2** is a simplified schematic diagram of a representative portion of apparatus like that shown in FIG. **1** in relation to some native tissue structures of a patient in accordance with the invention.

FIG. **3** is generally similar to FIG. **2** for some other native tissue structures of a patient.

FIG. **4** is a simplified elevational view of another illustrative embodiment of apparatus in accordance with the invention. FIG. **4** shows the depicted apparatus in its collapsed/pre-expanded state, and as though cut along a vertical line and then laid out flat.

FIG. **5** is generally similar to FIG. **4** for another illustrative embodiment in accordance with the invention.

FIG. **6** is a simplified elevational view of another illustrative embodiment of apparatus in accordance with the invention.

FIG. **7** is a simplified perspective view of another illustrative embodiment of apparatus in accordance with the invention.

FIG. **8** is a simplified perspective view showing an illustrative embodiment of another component added to what is shown in FIG. **7** in accordance with the invention.

FIG. **9** is generally similar to FIG. **8**, but shows an alternative embodiment with additional possible features in accordance with the invention.

FIG. **10** is generally similar to FIG. **9**, but shows an illustrative embodiment of more components added to what is shown in FIG. **9** in accordance with the invention.

FIG. **11** is a simplified perspective view showing in more detail a representative portion of the components that are added in FIG. **10**.

FIG. **12** is a simplified perspective view of another illustrative embodiment of apparatus in accordance with the invention.

FIG. **13** is a simplified perspective view of another illustrative embodiment of apparatus in accordance with the invention.

FIG. **14** is a simplified elevational view of still another illustrative embodiment of apparatus in accordance with the invention.

FIG. **15** is generally similar to FIG. **14**, but shows an illustrative embodiment of more components added to what is shown in FIG. **14** in accordance with the invention.

FIG. **16** is a simplified elevational view of another illustrative embodiment of apparatus in accordance with the invention.

FIG. **17** is a simplified elevational view of another illustrative embodiment of apparatus in accordance with the invention.

FIG. **18** is a simplified elevational view of another illustrative embodiment of a prosthetic heart valve in accordance with the invention.

FIG. **19** is a simplified perspective view of an embodiment like that shown in FIG. **18** with other possible elements added in accordance with the invention.

FIG. **20** is a simplified elevational view of another illustrative of a prosthetic heart valve in accordance with the invention.

FIG. **21** is a simplified perspective view of another illustrative embodiment of a component for a prosthetic heart valve in accordance with the invention.

FIG. **22** is a simplified perspective view of another illustrative embodiment of a prosthetic heart valve in accordance with the invention.

FIG. **23** is a simplified perspective view of another illustrative embodiment of a prosthetic heart valve in accordance with the invention.

FIG. **24** is a simplified perspective view of another illustrative embodiment of a component for a prosthetic heart valve in accordance with the invention.

FIG. **25** is generally similar to FIG. **24** for still another illustrative embodiment of a component for a prosthetic heart valve in accordance with the invention.

FIG. **26** is a simplified elevational view of yet another illustrative embodiment of a component for a prosthetic heart valve in accordance with the invention.

FIG. **27** is a simplified perspective view of still another illustrative embodiment of a prosthetic heart valve in accordance with the invention.

FIG. **28** is a simplified cross section of a typical patient tissue structure that is useful for explaining certain principles of the invention.

DETAILED DESCRIPTION

Certain components of an illustrative embodiment of a prosthetic heart valve **10** in accordance with the invention are shown in FIG. **1**. Valve **10** is designed for use as a replacement for a patient's native aortic valve. (Other valve types will be considered later in this specification.) FIG. **1** shows valve **10** in its expanded condition, i.e., the condition that the valve has when implanted in the patient. The depiction of valve **10** that is provided in FIG. **1** may omit certain components that the valve may have, but to some extent this is done to better reveal the components that are depicted in FIG. **1**. More information will be provided about these possibly omitted components later in this specification. Also, FIG. **1** shows by representative arrows **42** and **44** that certain parts of the structure shown in the FIG. may deflect farther out and down (in the case of the parts associated with arrows **42**) or farther out and up (in the case of the parts associated with arrows **44**) than happens to be shown in FIG. **1**. This will also be explained in more detail later in this specification.

Among the components of valve **10** are an annular metal structure **20/30/40**, and a leaflet structure **100**. Metal structure **20/30/40** forms a complete, continuous annulus around a longitudinal axis (not shown) that passes through the center of the valve. This central longitudinal axis is vertical, given the orientation of the valve shown in FIG. **1**. Structure **20/30/40** can be reduced in annular size from the size shown in FIG. **1** by compressing that structure in the annular or circumferential direction. When this is done, structure **20/30/40** shrinks by partial collapse of the diamond-shaped cells **22** and **46** of aortic portion **20** and annulus portion **40**. Later FIGS. will show examples of how such cells and/or other collapsible shapes can collapse or shrink in a direction that is annular of the valve. In other words, when the structure is thus made to shrink in the annular direction, the length of the perimeter measured around the outside of the valve becomes smaller. There is no significant change in the overall topological shape of the valve, especially metal structure **20/30/40**, between its large and small perimeter sizes or at any time as it transitions between those sizes. For example, if the valve is approximately a circular annulus in its full (FIG. **1**) size, it remains an approximately circular annulus as it is reduced to its smaller perimeter size. It is preferred that there be no folding, wrapping, overlapping, or

other major topological shape change of metal structure **20/30/40** to reduce its perimeter size or to subsequently re-expand it.

The above-described changes (i.e., collapsing and re-expanding) of metal structure **20/30/40** are preferably all elastic deformations. For example, metal structure **20/30/40** can be resiliently biased to have the size and shape shown in FIG. **1**. In such a case, collapsing of metal structure **20/30/40** to the above-mentioned smaller perimeter, annular, or circumferential size can be by elastic deformation of the metal structure, e.g., by confining metal structure **20/30/40** in a tube having a smaller perimeter than the full FIG. **1** size of the valve. Such a tube can be part of apparatus for delivering the valve into a patient. When the valve is pushed or pulled out of the tube, metal structure **20/30/40** automatically, elastically, re-expands to the full size shown in FIG. **1**. Because such a delivery tube can be smaller than the full size of the valve, the valve can be delivered into the patient less invasively than would be possible if the valve was only capable of always remaining full size as shown in FIG. **1**.

As an alternative or addition to full elastic compression and self-re-expansion, re-expansion may be at least partly assisted by other means. For example, an inflatable balloon on a catheter may be used to assist valve **10** to re-expand to its full size. Such a balloon may be temporarily positioned inside valve **10** to accomplish this. This may be done either because the elastic re-expansion is not quite strong enough to get the valve back to full size when adjacent to surrounding native tissue of the patient, because some plastic re-expansion is required to get the valve back to full size, to help ensure that the valve does in fact firmly seat in and engage the desired surrounding native tissue at the implant site, or for any other reason. For the most part it will be assumed herein that all or substantially all compression and re-expansion are elastic, but the possibility of some plastic compression and re-expansion is also contemplated as mentioned earlier in this paragraph.

We turn now to a description of the various parts of metal structure **20/30/40**. Part **20** is intended for implantation in the patient's native aorta downstream from the native aortic valve location, and also downstream from the patient's native valsalva sinus. Part **20** may therefore be referred to as the aortic portion of the valve or of metal support structure **20/30/40**. Portion **20** is a completely annular (continuous) structure, with the ability to annularly collapse and re-expand as described earlier in this specification. Portion **20** is made up principally of an annular array of parallelogram- or diamond-shaped cells **22**, which give portion **20** the ability to annularly compress and re-expand as described.

Part **40** is intended for implantation in the patient's native aortic valve annulus. Part **40** may therefore be referred to as the annulus portion of the valve or of metal support structure **20/30/40**. Part **40** is also a completely annular (continuous) structure, with the ability to annularly collapse and re-expand as described earlier in this specification. Part **40** is again made up primarily of an annular array of parallelogram- or diamond-shaped cells **46**, which give portion **40** the ability to annularly compress and re-expand as described.

Part **40** also includes three commissure post members **50** that are spaced from one another (e.g., approximately equally) around the valve. Each commissure post member **50** is intended for implantation at the approximate angular or circumferential location of a respective one of the patient's native aortic valve commissures. Like the native commissures, posts **50** are structures at which adjacent ones of the three leaflets of structure **100** came together in pairs. The blood inflow edge portions (lower as viewed in FIG. **1**) of each leaflet are also secured to other structure of the valve below posts **50**. The blood outflow edge portions of leaflets **100** (upper as viewed in FIG. **1**) are free (except for their end attachments to a respective pair of posts **50**). These free edges can come together to close the valve when blood pressure downstream from the valve is greater than blood pressure upstream from the valve. When the blood pressure differential reverses, the greater upstream blood pressure pushes the free edges of the leaflets apart, thereby opening the valve to allow blood flow through it.

Leaflet structure **100** is typically made of three flexible leaflet sheets. The material of these sheets can be any known flexible leaflet material such as appropriately treated natural tissue, a flexible polymer, or the like.

Each of commissure posts **50** is preferably at least partly cantilevered up (in the blood flow direction) from remaining structure of part **40**. For example, toward its blood inflow (lower) end, each of posts **50** may be attached to other structure of part **40** only near and/or below the middle of that part in the longitudinal (vertical) direction. At least the upper (blood outflow) end portion of each post **50** is therefore cantilevered from that post's lower-end-portion connections to other structure of part **40**. The upper end portion of each post **50** is accordingly preferably a free end (i.e., without any metal connection to other adjacent metal structure of part **40**). This has a number of advantages. One of these advantages is that it makes at least the upper portions of posts **50** at least somewhat independent of the other metal structure **20/30/40** of the device. This makes it possible for at least the upper portions of posts **50** to have properties like flexure characteristics, deflection characteristics, final location characteristics, etc., that can be optimized for the purposes that these post portions must serve, while other portions of metal structure **20/30/40** can be relatively independently optimized in these various respects for the various purposes that these other portions of structure **20/30/40** must serve. As an example of this, it may be desirable for the upper portions of posts **50** to stand relatively straight up and to have flexibility that is optimized for absorbing stress from the lateral edges of the leaflets **100** that are attached to those posts. At the same time, it may be desirable for other portions of metal structure **20/30/40** that are at the same general level along the longitudinal axis of the valve to flare radially out to various degrees. This will be described in more detail later in this specification. But just to complete the point that has been started here, it may be desired for the upper portions of cells **46** to be strong enough to hold back native leaflets and/or native leaflet remnants, and/or to deflect down onto the blood outflow surface of the native valve annulus (especially in cases in which the native leaflets have been wholly or largely removed). Similarly, it may be desirable for the members of strut structures **30** to begin to incline radially outwardly as they extend toward circumferentially larger aortic portion **20** and/or as they pass through the patient's native valsalva sinus, which is also circumferentially larger than the native valve annulus.

Clarification of a point of terminology may be appropriate here. When this specification speaks of a structure extending radially outwardly or the like, this does not necessarily mean that this structure is exactly perpendicular to a longitudinal axis extending in the blood flow direction through the valve. It may only mean that the structure has at least some component of alignment that is radial of the valve, i.e., that the structure (or a geometric projection of the structure) forms some angle with the above-mentioned longitudinal axis. In short, as a general matter, a "radially extending structure" or the like does not have to be fully or exactly

radial of the above-mentioned longitudinal axis, but may instead have only some vector component that is radial of that axis.

The aortic portion **20** and the annulus portion **40** of metal structure **20/30/40** are connected to one another by what may be termed struts or strut structures **30**. In the illustrative embodiment shown in FIG. **1** there are six of these struts **30**. They are in three pairs, with each pair being adjacent to a respective one of the three commissure posts **50**. More particularly, the two struts **30** in each pair are preferably located adjacent (and relatively close to) respective opposite sides of the associated post **50**. This arrangement leaves relatively large open areas (in the circumferential direction) between the pairs of struts **30**. In other words, the distance in the circumferential direction between the struts **30** in any pair of those struts is preferably less than the circumferential distance between the two circumferentially closest struts in any two different pairs of those struts. Because commissure posts **50** are angularly or rotationally aligned with the patient's native aortic valve commissures, and because struts **30** pass through the patient's native valsalva sinus relatively close to longitudinal projections of posts **50**, struts **30** are thus located to pass through the valsalva sinus (typically close to or at the wall of the valsalva sinus) along paths that are circumferentially spaced from the ostia of the patient's coronary arteries. In other words, struts **30** are preferably located in the circumferential direction to pass through the valsalva sinus without any possibility of a strut obstructing the ostium of a coronary artery. (Although patient anatomy can vary in this respect, the coronary artery ostia are typically located in the valsalva sinus between the native aortic valve commissures (or between longitudinal projections of the native aortic valve commissures). See also the later discussion of FIG. **28**, which discussion applies to embodiments of the kind generally illustrated by FIG. **1**. In particular, in the terms later discussed in connection with FIG. **28**, all material of structure **30** at the level of the coronary artery ostia should be confined to areas W as shown in FIG. **28**.)

In addition to the characteristics that are mentioned above, each of struts **30** is preferably serpentine in the longitudinal direction (i.e., as one proceeds along the length of any strut **30** from annulus portion **40** to aortic portion **20**, the strut deviates from a straight line, first to one side of the straight line, then to the other side of the straight line, then back to the first side, and so on). One of the benefits of this type of strut configuration is that it can increase the lateral flexibility of structure **20/30/40**, especially the lateral flexibility of strut portion **30** between portions **20** and **40**. Lateral flexibility means flexibility transverse to a longitudinal axis that is parallel to blood flow through the valve. Prior to and during implantation, this lateral flexibility can help the valve more easily follow curves in instrumentation that is used to deliver the valve into the patient. After implantation, this lateral flexibility can help each of portions **20** and **40** seat more concentrically in its respective portion of the patient's anatomy, which portions may not be exactly perpendicularly concentric with one single, common, central longitudinal axis.

As shown in FIG. **1**, the upper end of each strut **30** may connect to the lower end (or apex) of one of the cells **22** of aortic portion **20**. The lower end of each struts **30** may similarly connect to the upper end (or apex) of one of the cells **46** of annulus portion **40**. It should be noted, however, that especially at the lower end of strut structure **30** there are other cells **46** of annulus portion **40** that have no struts **30** connected to their upper ends or apexes. For example, arrows **42** are shown adjacent to the upper ends of two representative ones of cells **46** of this kind. These are the cells **46** whose upper portions can be configured to deflect or project radially outwardly (as indicated by the arrows **42**) for such purposes (mentioned earlier, and also in more detail later) as holding back any remaining native leaflet material and/or clamping down on the blood outflow side of the patient's native valve annulus.

From the foregoing, it will be seen that the features of valve **10** for holding the valve in place in the patient can include any or all of the following: (1) the radially outward projection of some or all of the lower portions of annulus cells **46** adjacent the blood inflow side of the native aortic valve annulus; (2) the radially outward projection of the upper portions of at least some of the upper portions of annulus cells **46** adjacent possibly remaining native aortic leaflet tissue and/or adjacent the blood outflow side of the native aortic valve annulus; (3) the general radial outward expansion of annulus portion **40** against the native valve annulus; (4) the radial outward expansion of aortic portion **20** to annularly engage the inner wall surface of the aorta downstream from the valsalva sinus; and (5) the possible engagement of the inner wall surface of the valsalva sinus by strut structures **30** passing through that sinus. Although not shown in FIG. **1**, it is possible to add to any suitable portion(s) of metal structure **20/30/40** barbs that project out from other adjacent structure so that they additionally engage, dig into, and/or penetrate tissue to give the implanted valve additional means for maintaining its position in the patient.

Note also that in addition to possibly engaging possibly remaining native aortic valve leaflet tissue, valve **10** has many structures for pushing any such remaining tissue radially outwardly away from possible interference with prosthetic leaflet structure **100**. These structures include the upper portions of all of cells **46** and the lower portions of all of struts **30**.

There are some other possible features of valve **10** that have not yet been mentioned. One of these aspects is the provision of apertures like **52** through commissure posts **50** (and possibly other portions of metal structure **20/30/40**) for facilitating the attachment (e.g., using suture material or other similar strand material) of leaflet structure **100** to the metal structure. Other layers of material such as tissue, fabric, or the like may also be attached to various parts of metal structure **20/30/40** for various purposes. These purposes may include (1) helping to prevent, reduce, or cushion contact between leaflet structure **100** and metal structure **20/30/40**; (2) helping to improve sealing between the valve and the surrounding native tissue (e.g., to prevent paravalvular leakage); and (3) helping to promote tissue in-growth into the implanted valve. Limited examples of such additional layers of material are shown in FIG. **1** in the form of lower fabric skirt **110** and blood inflow edge sealing ring **120**. Both of structures **110** and **120** extend annularly around the outside of the lower (blood inflow) edge of valve **10**. Structures like **110** and **120** may be held to metal structure **20/30/40** by sutures or other similar strand-like material, and apertures (like **52**) through the metal structure (or other features of the metal structure) may be used to provide anchoring sites for such sutures or the like. Still other possible aspects of valve **10** will be discussed in connection with later FIGS.

A possibly important feature of valves in accordance with the present invention is that they can include a structure near the blood inflow edge for clamping adjacent native tissues in a particular way. In particular, the upper and lower portions

of at least some of cells **46** can both pivot toward one another from a common central location. This is illustrated schematically in FIGS. **2** and **3**.

FIG. **2** shows the somewhat simpler case in which the patient's native aortic valve leaflets have been removed prior to implanting valve **10**. The native tissue structures that are visible in FIG. **2** are a portion **220** of the wall of the left ventricle, a portion **210** of the aortic valve annulus, and a portion **230** of the wall of the valsalva sinus. The upper portion of a representative cell **46** from FIG. **1** is shown schematically in FIG. **2** by member **142**. The lower portion of that cell is shown schematically by member **144**. Members **142** and **144** can pivot toward one another about central pivot point **143**. As in FIG. **1**, this is again indicated by arcing arrows **42** and **44**. Thus members **142** and **144** initially form a relatively large, open jaw structure, the two jaws of which can be released to resiliently pivot toward one another to clamp down on any tissue within their reach. In the case of FIG. **2**, this can include some of the tissue of sinus wall **230** and the upper surface of annulus **210** (for upper pivoting member **142**), and some of the tissue of left ventricle wall **220** and the lower surface of annulus **210** (for lower pivoting jaw member **144**). Clamping force vector component diagrams in FIG. **2** indicate the nature of the clamping forces that can result from these kinds of tissue engagement. For example, member **142** can have a radially outward clamping force component **142***a* and a longitudinally downward clamping force component **142***b*. Similarly, member **144** can have a radially outward clamping force component **144***a* and a longitudinally upward clamping force component **144***b*. Opposing clamping force components **142***b* and **144***b* tend to clamp tissue between members **142** and **144**. But radially outward force components **142***a* and **144***a* also engage tissue and therefore also help to hold valve **10** in place in the patient.

FIG. **3** illustrates the somewhat more elaborate case in which native aortic leaflet tissue **240** (typically, or at least often, stenotic) remains in the vicinity of prosthetic valve **10** when the valve is implanted. FIG. **3** shows that in this type of situation upper member **142** both engages leaflet tissue **240** and helps to push it radially out of the way. Again, member **142** exerts both a radially outward force component **142***a* and a longitudinal (downward) force component **142***b* on the adjacent tissue (in this case leaflet tissue **240**). The behavior and effects of lower member **144** are similar to what is shown in FIG. **2** and described earlier. Thus again the structures of valve **10** exert both radial outward tissue engaging forces **142***a*/**144***a* and oppositely directed tissue clamping forces **142***b*/**144***b* to hold valve **10** in place in the patient.

Recapitulating and extending the above, the attachment method of the present design applies forces in the radial and longitudinal directions to clamp onto several anatomical features, not just annulus **210**. In doing this, a valve in accordance with this invention can maximize (or at least significantly increase) the orifice area at the annulus level for better blood flow. Another way of thinking about the present designs is not necessarily as "clamps," but rather as members of a stent that conform to the different diameters of different portions of the anatomy. Structures that only "clamp" tend to engage only both sides of the native annulus (like **210**), and do not also extend to and engage other tissue structures as in the present designs. The present structures also differ from "clamp" structures that terminate from a single pointed wire. Instead, in the present designs, the conforming members are formed from continuous strut members of the base (annulus portion **40**) of the stent. This can only be achieved with an annulus portion **40** that stays below the ostia of the coronary arteries and with commissure posts **50** that are "independent" of other structure of annulus portion **40** as was described earlier in this specification.

Still other features of the present valves that warrant emphasis are mentioned in the following. The annulus portion **40** of the present valves preferably expands as nearly as possible to the full size of the native valve annulus. The leaflet structure **100** is preferably mounted just inside annulus portion **40**. This helps the present valves avoid any stenotic character (such as would result from having the leaflet structure or some other structure on which the leaflet structure is mounted) spaced radially inwardly from annulus portion **40**. The present valves are thus ensured to have the largest opening for blood to flow through, which reduces the pressure gradient (drop) across the valve.

Note that at the level of the coronary artery ostia, the present valves have only very minimal non-leaflet structure **30**; and even that minimal non-leaflet structure is rotationally positioned to pass through the valsalva sinus where it will safely bypass the coronary artery ostia. Annulus portion **40** is preferably designed to be entirely upstream (in the blood flow direction) from the coronary artery ostia. Aortic portion **20**, on the other hand, is preferably designed to be entirely downstream from the coronary artery ostia (i.e., in the aorta downstream from the valsalva sinus). Some prior designs have much more extensive non-leaflet structures extending much farther into or through the valsalva sinus and therefore longitudinally beyond the coronary artery ostia. This is believed to be less desirable than the present structures.

The present valves preferably include "independent" commissure posts **50** that are "lined up" or aligned with (i.e., superimposed over) the native valve commissures. This also helps to ensure proper coronary artery flow, when combined with the fact that struts **30** are confined to being closely adjacent to posts **50** in the circumferential direction. Even relatively thin connecting members (like struts **30**) could partially block a coronary artery if not correctly positioned in the circumferential direction around the valsalva sinus. But this is avoided in the present valves by the principles and features mentioned, for example, in the immediately preceding sentences.

FIG. **4** shows another illustrative embodiment of metal support structure **20**/**30**/**40**. FIG. **4** shows this structure as though cut along its length and then laid flat. FIG. **4** also shows this structure in the condition that it has in its circumferentially collapsed condition. Thus, for example, the sides of what will be diamond-shaped cells **22** and **46** in the re-expanded valve are, in FIG. **4**, collapsed down to being parallel with one another. Again, the fact that FIGS. like FIG. **4** show structures as though cut longitudinally and laid flat is only for ease and convenience of depiction. In actual fact these structures are complete and continuous annular structures like the structure **20**/**30**/**40** shown in FIG. **1**.

Note that in the FIG. **4** design there are eyelets **24** in aortic section **20** for attachment of material and/or attachment of wires/sutures for a delivery system. On annulus section **40** the eyelets **48**/**52** can be used for attachment of the cuff, porcine buffer, and/or leaflets. FIG. **4** shows an annulus portion **40** with a "scalloped" inflow (lower) edge. This scalloped blood inflow edge is relatively "high" in the vicinity of the inflow end of each commissure post **50**, and relatively "low" between commissure post **50** inflow ends. ("High" means more downstream; "low" means more upstream.) This can help the implanted valve avoid affecting

the patient's mitral valve, which tends to be radially spaced from the aortic valve along a radius of the aortic valve that corresponds to the radial location of one of the aortic valve's commissures. Because the valves of this invention are preferably implanted with posts **50** superimposed inside the native valve commissures, this places one of the "high" portions **41** of the inflow edge adjacent the patient's mitral valve. The resulting recessing **41** of annulus portion **40** helps the prosthetic valve avoid interfering with the mitral valve.

FIG. **5** shows yet another illustrative embodiment of metal support structure **20/30/40**. FIG. **5** shows this embodiment in the same general way and condition as FIG. **4** shows its embodiment. Thus, as said in connection with FIG. **4**, the structure shown in FIG. **5** is actually a complete, continuous annulus, and the longitudinally cut and flattened depiction shown in FIG. **5** is only employed for simplicity and greater clarity.

The FIG. **5** embodiment again has eyelets **24** in the aortic section **20** for attachment of material and/or attachment of wires/sutures for a delivery system. Also, eyelets **48/52** on annulus section **40** can be used for attachment of the cuff, porcine buffer, and/or leaflets. As compared to the FIG. **4** design (in which connecting support struts **30** are connected to the downstream apexes of certain annulus portion cells **46**), in FIG. **5** the connecting support struts **30** are connected directly to posts **50**. The aortic portion **20** of the FIG. **5** embodiment also has two annular arrays of cells **22***a* and **22***b* (rather than only one annular array of such cells **22** as in the earlier embodiments). Array **22***a* is more downstream than array **22***b*, but these two arrays do overlap somewhat in the longitudinal direction by virtue of the cells in the two arrays having some intervening cell members (like representative member **23**) in common.

A typical way of making any of the support structures **20/30/40** of this invention is to laser-cut them from a tube.

FIG. **6** shows another illustrative embodiment of aortic portion **20**, in which the cells **22** of the mesh stent can expand against the ascending aorta. This structure may or may not be covered in tissue, polymer, and/or fabric (true for any of the embodiments shown and described herein).

FIGS. **7** and **8** show another illustrative embodiment of annulus portion **40**. This mesh stent has expandable cells that press against the native valve annulus and/or leaflets (if the native leaflets remain). Upper **142** and lower **144** portions of this stent clamp down on the native annulus and/or leaflets. This stent design is symmetrical around the circumference, but it may be asymmetrical to allow anatomical conformance with the mitral valve, for example. A cuff **110** made of fabric, tissue, or polymer may fully or partially encapsulate this stent as shown, for example in FIG. **8**.

FIGS. **9** and **10** show an embodiment of stent **40** that includes a set of barbs **43** on the top and/or bottom to further secure the stent in order to stop migration. A partial cuff **110** (FIG. **10**) allows the barbed tips **43** to be exposed to direct tissue contact for enhanced securing. The bottom section could be asymmetrical (e.g., as in FIGS. **4** and **5**) to mitigate any impingement on the mitral valve. An extra-thick, toroidal section **112** of the cuff allows extra sealing capacity to prevent paravalvular leakage.

FIG. **11** shows that toroidal section **112** of cuff **110** allows extra sealing capacity to prevent paravalvular leakage. This section could be made of extra fabric, tissue, or polymer. The chamber **114** inside section **112** can accommodate an injectable polymeric substance to aid in seating.

FIG. **12** shows another illustrative embodiment of the aortic holding portion **20**. In this case portion **20** is a metallic or polymeric expandable wire form with many of the same attributes discussed with the mesh stent.

FIG. **13** shows another illustrative embodiment of annulus/leaflet holding portion **40**. In this case portion **40** is a metallic or polymeric expandable wire form with many of the same attributes discussed with the mesh stent.

FIGS. **14** and **15** show an illustrative assembly of an aortic portion **20** and an annulus portion **40**. In FIG. **15** a pliable or semi-rigid reinforced fabric **30** connects the aortic portion **20** and the annulus/cuff portion **40/110/112** to allow somewhat independent movement. The tissue or synthetic leaflets **100** can then be attached to connecting section **30**. All of the disclosed variations allow for ample areas (like **130**) for blood to flow to the coronaries.

The variation shown in FIG. **16** does not include an aortic portion **20**. Instead, three independent commissure posts **50** allow for leaflet attachment (e.g., with the aid of apertures **52**), while the base **40** is secured in place as described earlier. Posts **50** can be lined up with the native commissures and (by virtue of the recesses like the one identified by reference number **41**) allow for an opening on the lower portion to be clear of chordae and the mitral valve. The posts **50** used to attach the leaflets may be solid or have any combination of holes, slots, and/or other apertures **52**.

Note that even for an embodiment like FIG. **16**, when used for an aortic valve, any non-leaflet portion of the valve (such as commissure posts **50**) that extends into the coronary sinus to the level of any coronary artery ostium is confined, in the circumferential direction, to locations that are well spaced from the coronary artery ostia. This is preferably accomplished by having all such non-leaflet structure confined (in the circumferential direction) to locations or areas that are at or circumferentially near the native aortic valve commissures (or downstream projections of those commissures). The circumferential width of each of these areas in which non-leaflet structure is permitted at the level of the coronary artery ostia is preferably less than the circumferential spacing at that level between circumferentially adjacent ones of those areas. It is not a problem for moving leaflet material to extend to or even beyond the level of the coronary artery ostia because the coronary arteries can fill with blood when the valve is closed. But no non-leaflet and therefore basically non-moving part of the prosthetic valve should be allowed to occupy any location at the level of the coronary artery ostia where that non-leaflet material may interfere with blood flow into the coronary arteries.

FIG. **28** illustrates the point made in the immediately preceding paragraph (and also elsewhere in this specification). FIG. **28** shows a cross section of a typical patient's valsalva sinus **300** at the level of the coronary artery ostia. The patient's native aortic commissures (or downstream projections of those commissures) are at locations **310***a-c*. The coronary artery ostia typically occur in bracketed areas **320**. Any non-leaflet structure of a prosthetic valve in accordance with this invention that is at the level depicted by FIG. **28** should be confined to areas W. The width of each of these areas in the circumferential direction (i.e., the dimension W) is preferably less than the distance S in the circumferential direction between any two circumferentially adjacent ones of these areas.

FIG. **17** shows another illustrative embodiment that is somewhat like the embodiments in FIGS. **1**, **4**, and **5** in that there is a continuous link **30** between aortic section **20** and annulus section **40**. In this embodiment link structure **30** itself allows for leaflet attachment, with the lower portion of each link **30** acting like a commissure post **50**. To mitigate leaflet abrasion at the attachment site in this or any other

embodiment, the stent may first be covered with fabric, followed by a thin layer of buffering tissue/polymer, and finally the leaflet tissue/polymer. The stent of the valve can be partially or completely covered in one or a combination of materials (polyester, tissue, etc.) to allow for better in-growth, abrasion protection, sealing, and protection from metal leachables like nickel from nitinol.

Most of the detailed discussion thus far in this specification has related to prosthetic aortic valves. However, certain aspects of what has already been said can also be applied to making prosthetic valves for other locations in the heart. The mitral valve is another valve that frequently needs replacement, and so this discussion will now turn to possible constructions for other valves such as the mitral valve.

In the case of the mitral valve (which supplies blood from the left atrium to the left ventricle), only the native valve annulus area (possibly including what is left of the native valve leaflets) is available for anchoring the prosthetic valve in place. There is nothing comparable to the aorta for additional downstream anchoring of a prosthetic mitral valve.

Structures of the types shown in FIGS. **7-11** and **13** are suitable for use in prosthetic mitral valves. In such use, annular structure **40** may be delivered into the native mitral valve annulus in a circumferentially collapsed condition and then re-expanded to the depicted size and condition in that annulus. The apex portions **142** of cells **46** at one end of structure **40** (e.g., the blood inflow end) project resiliently out and also pivot somewhat downstream as shown, for example, in FIG. **7** and engage the patient's tissue adjacent the inflow side of the patient's native mitral valve annulus. Apex portions **144** of cells **46** at the other end of structure **40** (e.g., the blood outflow end) project resiliently out and also pivot somewhat upstream and engage the patient's tissue adjacent the outflow side of the patient's native valve annulus. The tissue of and adjacent to the mitral valve annulus is thereby clamped between tissue clamping structures **142** and **144**. Barbs **43** may be added as shown in FIGS. **9** and **10** for additional tissue engagement and possible penetration to additionally help hold the valve in place in the mitral valve annulus. Other features (e.g., **110** and **120**) and principles discussed earlier in connection with FIGS. **7-11** and **13** apply to the possible mitral valve use of these structures and features.

An illustrative embodiment of a more fully developed prosthetic mitral valve **210** in accordance with the invention is shown in FIG. **18**. In this depiction of mitral valve **210**, its blood inflow end is down, and its blood outflow end is up. (This depiction may be regarded as "upside down" as compared to its orientation in a patient who is standing upright.) Analogous to what is shown in FIG. **16**, valve **210** has three commissure posts **50** that are cantilevered from annular structure **40**. Flexible valve leaflets **100** are attached to these posts (and elsewhere to other structure of the valve such as annular structure **40** and/or material that is used to cover structure **40**). Apertures **52** through posts **50** may be used to facilitate attachment (e.g., suturing) of the leaflets to the posts. Additional apertures **54** in posts **50** may be used as sites for or to facilitate attachment of chordae tendonae (native and/or artificial replacements) to the posts. This last point will be considered further as the discussion proceeds.

The posts **50** used to attach the leaflets can be solid or can have any combination of holes and/or slots. Three independent posts **50** (i.e., "independent" because cantilevered from annular structure **40**) allow for leaflet attachment, while the base **40** is secured in place as described earlier. Also, posts **50** can be lined up with the native anatomy for better leaflet opening clear of chordae and the aortic valve. Apertures **54** can be included near the downstream free ends of posts **50** for native and/or artificial chordae attachment. To mitigate leaflet abrasion at the attachment site, the stent **40** can first be covered with fabric, followed by a thin layer of buffering tissue/polymer, and finally the leaflet **100** tissue/polymer. As is true for all embodiments herein, the stent **40** of the valve can be partially or completely covered in one or a combination of materials (polyester, tissue, etc.) to allow for better in-growth, abrasion protection, sealing, and protection from metal leachables such as nickel from nitinol. The support structure **50** for the leaflets may be continuous from the clamping stent portion **40**. Alternatively, the leaflet support structure may be a separate section connected to clamping portion **40**, or it may be frameless.

FIG. **19** shows an example of how artificial and/or native chordae **220** can be attached prior to, during, or after implanting prosthetic mitral valve **210**. These chordae attachments are made at or near the downstream free ends of posts **50**. Chordae **220** can be adjusted through cored papillary muscles and/or through a port made in the apex of the beating heart.

FIG. **20** shows an alternative embodiment of prosthetic mitral valve **210** in which chordae **230** can be attached to an extended free edge **102** of the leaflets prior to, during, or after implanting of the valve in the patient. Once again, chordae **230** can be adjusted through cored papillary muscles and/or through a port made in the apex of the beating heart. The redundant coaptation portions **102** of the leaflets can be reinforced tissue (e.g., a double layer or thicker tissue), or if the leaflet is a polymer, it can be reinforced by greater thickness and/or fibers.

FIG. **21** shows that the stent **40** design can include apertures **48** around the center portion of the stent to allow for cuff, leaflet, and chordae attachment around the circumference of the stent. FIG. **22** shows that the edge of cuff **110** can follow the edge shape of stent **40** to allow for passage of chordae and reduction of interference of other anatomy, while also allowing greater flexibility of annular structure **40**. FIG. **23** shows chordae **240** extending from apertures like those shown at **48** in FIG. **21**.

FIG. **24** illustrates the point that variations in stent cell **46** geometry around the circumference of annular structure **40** can reduce impingement on or of the aortic valve, chordae, and the coronary sinus. Additionally, extended portions (e.g., **244**) of some cells may allow for greater holding force in certain parts of the anatomy such as in the atrial appendage.

FIGS. **25** and **26** show other variations in the shape of annular structure **40** that can allow for better conformance to the mitral valve anatomy. For example, FIG. **25** shows an asymmetric shape, while FIG. **26** shows a symmetric saddle shape.

FIG. **27** shows that a valve **210** with an elliptical shape may also conform better to the mitral valve anatomy than a circular-shaped valve. Additionally, instead of a tri-leaflet design, FIG. **27** shows that a bi-leaflet design **100'** can be used (leaflets shown open in FIG. **27**). Once again, chordae **220** can be attached at commissure posts **50**, and the edge of cuff **110** can be contoured to follow the edge of stent **40**.

Although the structures shown in FIGS. **18-27** are described primarily as mitral valve structures, it will be understood that this is only illustrative, and that various structures and principles illustrated by or in these FIGS. can be employed in other types of prosthetic heart valves (e.g., in prosthetic aortic valves).

Briefly recapitulating some of what has been said in somewhat different terms, it will be seen that in many embodiments of the invention, at least the portion **40** of the prosthetic valve that goes in the patient's native valve annulus includes an annular array of generally diamond-shaped cells **46**. Upstream apex portions **144** of at least some of these cells are resiliently biased to deflect radially outwardly from at least some other portions of structure **40**. Downstream apex portions **142** of at least some of these cells are similarly resiliently biased to deflect radially outwardly from at least some other portions of structure **40**. This allows the valve to clamp tissue of the patient between the upstream and downstream apex portions that thus deflect outwardly.

Each of the above-mentioned apex portions comprises two spaced-apart members that join at an apex of that apex portion. For example, in FIG. **7** the two spaced-apart members of one representative downstream apex portion are identified by reference letters b and c, and the apex where those members join is identified by reference letter a.

Still more particularly, the resiliently biased, radially outward deflection of each upstream apex portion **144** typically includes a downstream component of motion of that upstream apex portion (in addition to a radially outward component of motion). This is illustrated, for example, by the arcuate arrows **44** in FIGS. **1-3**. Similarly, the resiliently biased, radially outward deflection of each of downstream apex portion **142** typically includes an upstream component of motion of that downstream apex portion (in addition to a radially outward component of motion). This is illustrated, for example, by the arcuate arrows **42** in FIGS. **1-3**. The result of this is that the upstream and downstream apex portions begin as jaws that are relatively far apart and wide open. They then effectively pivot toward one another to clamp tissue therebetween.

References herein to an annular perimeter of a structure being changeable in length mean that the perimeter increases or decreases in size without going through any major topological change. In other words, the shape of the structure remains basically the same, and only the perimeter size changes. For example, the shape may be always basically circular. There is no folding or wrapping of the structure to change its perimeter size. The shape either basically shrinks down or expands out. A minor exception to the foregoing is that ellipses and circles are regarded herein as having the same basic topology. Thus an ellipse may shrink to a circle, for example, without that constituting "a major topological change."

It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, the particular patterns of stent cells like **22** and **46** shown herein are only illustrative, and many other stent configurations can be used instead if desired. It will be appreciated that the valves of this invention can, if desired, be implanted in a patient less invasively. For example, the valves of this invention can be implanted percutaneously, trans-apically, or surgically, and with or without resected and/or debrided leaflets. Depending on the embodiment, the valve can be collapsed in a variety of configurations before deployment in a single- or multi-stage process. Access can be achieved, for example, through the femoral artery, abdominal aorta, or the apex of the heart.

The invention claimed is:

1. A prosthetic heart valve, comprising:

a stent having an inflow end, an outflow end, an expanded condition, a collapsed condition, and a length in a longitudinal direction from the inflow end to the outflow end, the stent including an annulus portion having a plurality of closed perimeter cells adjacent the inflow end, an aortic portion having a plurality of closed perimeter cells adjacent the outflow end, and an intermediate open area between the annulus portion and the aortic portion that, in the expanded condition, is enlarged relative to the closed perimeter cells in the annulus portion and the closed perimeter cells in the aortic portion;

a plurality of valve leaflets operatively supported by the stent; and

a cuff connected to the stent and having an inside wall and an outside wall, the inside wall having a length in the longitudinal direction that is greater than a length of the outside wall in the longitudinal direction.

2. The prosthetic heart valve as claimed in claim **1**, wherein the inflow end of the stent has a first circumference in the expanded condition and the outflow end of the stent has a second circumference in the expanded condition, the second circumference being larger than the first circumference.

3. The prosthetic heart valve as claimed in claim **1**, wherein the inside wall of the cuff is disposed radially inward of the stent.

4. The prosthetic heart valve as claimed in claim **1**, wherein the inside wall of the cuff has an outflow edge that is spaced a first distance from the outflow end of the stent, and the outside wall of the cuff has an outflow end that is spaced a second distance from the outflow end of the stent greater than the first distance.

5. The prosthetic heart valve as claimed in claim **1**, wherein the stent includes a plurality of commissure features between the inflow end of the stent and the outflow end of the stent.

6. The prosthetic heart valve as claimed in claim **5**, wherein the cuff is disposed in the annulus portion of the stent between the inflow end and the commissure features.

7. The prosthetic heart valve as claimed in claim **1**, wherein the closed perimeter cells in the annulus portion of the stent are diamond-shaped in the expanded condition.

8. The prosthetic heart valve as claimed in claim **7**, wherein the closed perimeter cells in the aortic portion of the stent are diamond shaped in the expanded condition.

9. The prosthetic heart valve as claimed in claim **8**, wherein each of the closed perimeter cells in the aortic portion of the stent is larger than each of the closed perimeter cells in the annulus portion of the stent in the expanded condition.

10. The prosthetic heart valve as claimed in claim **1**, wherein the stent includes a plurality of intermediate open areas between the annulus portion and the aortic portion.

11. A prosthetic heart valve, comprising:

a stent having an inflow end, an outflow end, an expanded condition, a collapsed condition, and a length in a longitudinal direction from the inflow end to the outflow end, the stent including an annulus portion adjacent the inflow end and an aortic portion adjacent the outflow end, the annulus portion having a plurality of closed perimeter cells each defining a first open area in the expanded condition, the aortic portion having a plurality of closed perimeter cells each defining a second open area in the expanded condition, and the stent having a plurality of third open areas between the annulus portion and the aortic portion, each of the third

open areas in the expanded condition being larger than each of the first open areas and each of the second open areas;

a valve element positioned within the stent; and

a cuff in the annulus portion of the stent and having a first wall and a second wall radially outward of the first wall, the first wall having a first length in the longitudinal direction less than the length of the stent such that an outflow end of the first wall is positioned at a first spaced distance from the outflow end of the stent and the second wall having a second length in the longitudinal direction less than the first length.

12. The prosthetic heart valve as claimed in claim **11**, further comprising a plurality of commissure features spaced from one another in a circumferential direction of the stent between the inflow end of the stent and the outflow end of the stent.

13. The prosthetic heart valve as claimed in claim **11**, wherein each of the second open areas is larger than each of the first open areas.

14. The prosthetic heart valve as claimed in claim **13**, wherein each of the first open areas is diamond shaped in the expanded condition and each of the second open areas is diamond shaped in the expanded condition.

15. The prosthetic heart valve as claimed in claim **11**, wherein the annulus portion of the stent in the expanded condition has a first diameter and the aortic portion of the stent in the expanded condition has a second diameter larger than the first diameter.

16. The prosthetic heart valve as claimed in claim **11**, wherein the valve element includes a plurality of leaflets that collectively have a closed condition to keep blood from flowing through the prosthetic heart valve, and an open position to permit blood to flow through the prosthetic heart valve.

17. The prosthetic heart valve as claimed in claim **11**, wherein, in the expanded condition of the stent, each of the third open areas of the stent has a first maximum dimension in a circumferential direction of the stent and the stent has a second maximum dimension in the circumferential direction between each adjacent pair of third open areas, the second maximum dimension being less than the first maximum dimension.

18. The prosthetic heart valve as claimed in claim **11**, wherein an outflow end of the second wall is spaced from the outflow end of the stent by a second distance greater than the first distance.

19. The prosthetic heart valve as claimed in claim **11**, wherein the first wall of the cuff is disposed radially inward of the stent and the second wall of the cuff is disposed radially outward of the stent.

20. The prosthetic heart valve as claimed in claim **11**, wherein the cuff comprises a material selected from the group consisting of tissue, a fabric or a polymer.

21. A prosthetic heart valve, comprising:

a stent having an inflow end, an outflow end, an expanded condition, a collapsed condition, and a length in a longitudinal direction from the inflow end to the outflow end, the stent including an annulus portion adjacent the inflow end and an aortic portion adjacent the outflow end, the annulus portion having a plurality of closed perimeter cells each defining a first open area in the expanded condition, the aortic portion having a plurality of closed perimeter cells each defining a second open area in the expanded condition, and the stent having a plurality of third open areas between the annulus portion and the aortic portion, each of the third open areas in the expanded condition being larger than each of the first open areas and each of the second open areas, the third open areas including struts that, in the expanded condition, incline radially outwardly as one moves along the struts toward the outflow end of the stent;

a valve element positioned within the stent; and

a cuff connected to the stent and having an inside wall and an outside wall, the inside wall having a length in the longitudinal direction that is greater than a length of the outside wall in the longitudinal direction.

22. A prosthetic heart valve, comprising:

a stent having an inflow end, an outflow end, an expanded condition, a collapsed condition, and a length in a longitudinal direction from the inflow end to the outflow end, the stent including an annulus portion adjacent the inflow end, an aortic portion adjacent the outflow end, and an intermediate portion between the annulus portion and the aortic portion, the stent including a plurality of closed perimeter cells each defining an open area in the expanded condition, the intermediate portion of the stent having cells with the largest open areas;

a valve element positioned within the stent; and

a cuff connected to the stent and having an inside wall and an outside wall, the inside wall having a length in the longitudinal direction that is greater than a length of the outside wall in the longitudinal direction.

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